Reconstructive options in revision surgery of failed total hip arthroplasties

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RECONSTRUCTIVE OPTIONS IN REVISION SURGERY OF FAILED TOTAL HIP ARTHROPLASTIES

Een wetenschappelijke proeve op het gebied van de Medische Wetenschappen

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Berend Willem Schreurs

geboren op 2 juni 1957 te Winterswijk

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Contents

CHAPTER 1

Introduction

Sucess and Failure of Revision THA

Osteoarthritis of the hip is a common cause of severe disablement in elder people. Total hip arthroplasty (THA) reduces the pain in the affected hip, restores the motion and improves the quality of life significantly (Wickland and Romanus, 1991, Laupacis et al., 1993). Total hip arthroplasty is attractive for the society at large as well, it is cost-effective as was proven in cost-to-benefit analyses (Keet,1987). Worldwide, several hundred thousands of hip arthroplasties are performed per year. In the Netherlands about 14.000 primary total hip arthroplasties are performed each year (SIG, 1993). However, all total hip arthroplasties will fail in time. There are multiple failure mechanism, however potential failure mechanism for both cemented and noncemented THA are alike (Huiskes, 1993a). If the patient survives his total hip arthroplasty, as can be expected in the younger patient, a new problem is born. Especially the more liberal use of arthroplasties in younger patients is the reason why, in a way, total hip arthroplasty is now threatened by its own success (Poss,1992).

Although a failed total hip prosthesis can be removed in most cases and replaced by another one during a revision operation, these present a number of problems. This dissertation concentrates on some aspects of revision surgery, and especially on the problems met on the femoral side.

The clinical outcome of revision surgery can not compete with the success of primary total hip arthroplasty. In a nation-wide Swedish study it was shown that 10 per cent of the primary total hip arthroplasties had to be revised within 10 years (Ahnfelt et al 1990). Revision surgery requires more operation time, more blood loss, and is associated with a higher rate of complications. The incidence of infection is doubled, with also higher incidences of dislocations, heterotopic ossifications, penetration and fractures of femur or acetabulum, and nerve lesions. The morbidity is increased (Hunter, 1986, JAMA Consensus Conference 1981). In addition, the long-term failure rate of cemented revision total hip replacement is higher than for primary THA. Hunter et al. (1979) presented 140 cases revised for aseptic loosening, dislocation or stem-fracture, with a dramatic infection rate of 22 per cent. Amstutz et al. (1982) presented 66 patients revised for aseptic loosening with a mean follow-up of 2.1 years (1-9 years). Nine per cent had already required a re-revision and in 20 per cent there were clear signs of radiographic loosening. Kavenagh et al. (1985) reviewed 166 hips revised for reasons other than infection. Mean follow-up was 4.5 years (1-10 years). Nine per cent had a second revision, roentgenographic analysis showed suspected loosening in 20 per cent of the acetabular components and 44 per cent of the femoral components. Callaghan et al. (1985) studied 139 hips revised for mechanical failure, which were followed for an average of 3.6 years (2-5 years). Roentgenographic loosening was seen in 18 per cent of the femoral and nine per cent of the acetabular components. Re-revisions were performed in 9 per cent. Pellici et al. (1985) reported 99 revisions for aseptic failure with an average follow-up of 8.1 years (5-12.5 years). Re-revision was done in 12 patients, the rate of mechanical failure, including those showing progressive radiolucency, was 29 per cent. The results of re-revision, or even third revisions, were unsatisfactory in 33 of the 53 second revisions and 5 of the 13 third revisions (Retpen et al.,1992). Cemented revisions in patients under 55 years resulted in a failure rate of 36-per cent after a mean follow-up of 4 years (Stroemberg et al. 1988). In another study Stroemberg et al. (1992) presented in 1992 the results of a Swedish nation-wide study of 204 cemented hip revisions for aseptic loosening in patients between 55 and 70 years at revision time. The average follow-up time was 7 years, operations were performed in the period 1979-1982. Re-revision or radiographically loose components occurred in 38 per cent of the hips. The survival rate at 8 years, with re-revision as defined end point, was 75 per cent. This important study clearly showed that revision surgery with cemented THA using conventional cementing techniques gives unsatisfactory results. Loosening rates were associated with previous bony defects, especially on the acetabular side. However, some recent studies showed better results. Marti et al. (1990) reported the results of 60 cemented revisions for aseptic loosening in a group of relatively old (average age at revision 71 years) patients. After an average follow-up of 8.9 years (5-14 years) 10 per cent were re-revised. Survivorship analysis showed a cumulative survival of 85 per cent at 14 years. In cases of bone stock loss of the acetabular roof, autogenous grafts were used. However, also taking into account radiological signs of loosening, the failure rate will probably be increased. Kershaw et al. (1991) presented a review of 276 cemented revisions for aseptic loosening, performed between 1977 and 1986 with a mean follow-up of 6 years (2.5-12 years). Eighteen hips required further revision. Survival at 5 years was 95 per cent and at 10 years 77 per cent. Engelbrecht et al. (1990) followed 138 revision for aseptic loosening for an average of 7.4 years (3-15.5). The revision rate in the relatively young patients (average age 59 years) was 8.8 per cent. However, signs of radiographic loosening rate were frequent (approx. 35 per cent). In none of these studies modern cementing techniques were applied. These techniques are suggested to improve the results of cemented THA. Examples are the use of a cement plug in the femur, cleansing the bone bed with a water pick , techniques to reduce the porosity of the cement like centrifugation or vacuum mixing and mechanical compression of the cement to facilitate the intrusion into the bone bed. Given the improved results after primary THA using these techniques (Rusotti et al.,1988), these cementing techniques may improve the results of revisions (Fuchs et al. 1988, Rubash and Harris, 1988).

In summary, although primary THA is relatively successfull, long-term loosening problems are likely to occur in all but old patients. Revision THA, however, is much less succesfull. In this dissertation, three methods are discussed which may improve the long-term endurance of cemented revision THA. One relates to the strength of cement, the second to cement removal during revision surgery, and the third to fixation of the revised components to the bone.

Fatigue strength of acrylic cement

Unfortunately, the mechanical properties of PMMA are not ideal; it has good load-carrying capabilities in compression but is weak in shear, tension, and fatigue resistance (Huiskes, 1993b). To improve the results of cemented THA, it is important to improve the fatigue strength of bone cement. The main factor which determines the fatigue strength of polymethylmethacrylate bone cement, besides the quality of the material itself, is the porosity. Pores in acrylic cement can be caused by three mechanism: by air solutions in the monomere liquid, by entrapment of air in the cement dough during stirring, and by boiling of monomere (de Wijn, 1982). By reducing the porosity and thus increasing the fatigue strength, the clinical results of cemented total hip arthroplasties can probably be improved. It was suggested that this could be effective especially on the femoral side (Wixon, 1993). To reduce the porosity, several techniques have been suggested and are used in the clinical setting. Centrifugation of bone cement was introduced by Gates et al. (1983), Lidgren et al. (1984) suggested to use a vacuum mixing technique. In Chapter 2 the results of four acrylic cement preparation techniques were investigated for their effects on cement porosity: hand mixing, pressurization in a pneumatic pistol, centrifugation, and vacuum mixing. These techniques were tested with low, medium and high viscosity bone cements.

Removal of prosthesis and bone cement

The first problem met during a revision is how to remove the primary stem and the bone cement from the femur. Conversely to the suggestion made in the term "aseptic loosening", in most cases the stem and the cement can not simply be taken out.

For stems with a fixed head several extraction sets are available. In other cases the stem can be removed using the collar as a driving platform for a punch and a mallet. Sometimes a hook can be inserted through a hole in a stem. In general, after some blows with a hammer, the stem can be removed.

In cases with a stem fracture, the extraction is more difficult. Wroblewski (1979) suggested to extract the broken stem by using a threaded stud-bolt remover, a technique which is only applicable in stainless steel stems. Harris et al. (1981) introduced a technique using a high-speed drill, a technically demanding process. Collis and Dubrul (1984) used a trephine to cut circumferentially around the fractured stem. Mollan and McClelland (1984) used plastic drill guides to control the high speed drills. Alternatives for these techniques are windows which can be made in the proximal femur. First the cement around the stem is distracted and next the stem can be driven proximally. A modification of this technique, using only a very small window, was presented by Moreland et al. (1986), who used high speed drills and a tungsten carbide punch.

After the stem, the bone cement has to be removed. This is still a very demanding task, requiring high skills, and very time consuming. Frequent complications of cement extraction are femoral fracture, penetration of the cortical bone by a fausse route, and additional loss of the already affected bone stock. Several methods have been proposed. Most often the cement is removed by using special sets of chisels and osteotomes (Stühmer, 1976). This system is convenient for the proximal bone cement. However, the problem is how to remove the distal cement and, if present, the cement plug. Slooff and Lindner (1974) described an extraction set for this problem, using self tapping rods. Razzano (1977) suggested to use variable sized carbide drills. To reduce the chances for shaft perforations, Eftekhar (1977) used a guide and drill system with a clamp on the proximal femur. High speed drills were introduced by Harris and Oh (1978). However, these high speed drills are very aggressive. When deflected from the hard cement to the softer cortical bone, perforations are easily made. To prevent that, the use of high speed drills under biplane fluoroscopy was suggested (Turner et al., 1987). Because of these problems, alternative techniques have been suggested as well. Ultrasound methods have been tried to make removal of cement and the distal plug easier (Nieder et al.,1979). Although many technical problems were met (Weber et al., 1987), these systems are now available for clinical use (Klapper et al.,1992). Carbon dioxide laser techniques have been reported (Beacon et al.,1979, Booth et al. 1987) and are still under investigation. At the moment, this technique is not practical as yet; it requires an elaborate set-up and considerable practice (Sherk, 1993). Recently, the extracorporeal shock wave lithotryptor (ESWL), successfully used in Urology to disintegrate kidney stones, was proposed to facilitate the removal of bone cement (Karpman et al., 1987, Weinstein et al. 1988). Probably, the cement-bone interface or the bone cement itself reduces in strength after a pre-operative treatment by ESWL, thus facilitating the revision procedure. However, very little is known about the effects of ESWL on bone and bone cement. In collaboration with the Urologic Department a project was started to obtain information about the effect of these high energy shock waves on acrylic bone cement. This experiment is described in Chapter 3.

Improved fixation for revision components

The main problem in revision surgery of failed arthroplasties is the bone stock loss which is induced by the loosening process itself and by the procedures to remove the prosthesis and cement, often just leaving a smooth and sclerotic endosteal wall. The reduction in cement-bone interface shear strength in revision arthroplasties may be a major cause of the high re-revision rate (Dohmae et al. 1988). Given these disappointing results, and the very promising short-term results of cementless hip devices, cementless hip replacements became popular in revisions of cemented hips. Some authors (Hungerford and Jones, 1988) have advocated the use of only noncemented techniques in cemented revision surgery cases. However, the short-term results of noncemented revisions are precarious, with femoral loosening up to 9.5% after one year (Gustilo et al. 1988, Harris et al. 1988, Hedley et al. 1988).

Based on the experience of Parker and Hastings (1974) and McCollum and Nunley (1978) with bone grafts in acetabular protrusion, our institution started in 1978 with a bone grafting technique, using impacted morsellized bone chips in combination with a cemented cup (Slooff et al. 1984). This technique was applied both to cavitary and segmental defects, always trying to reconstruct the center of rotation of the hip to the anatomic location. This method showed good clinical results if used in protrusio acetabuli in patients with rheumatoid arthritis (Kinzinger et al., 1991). There were no failures in 27 primary hips with RA with a mean follow-up of 5 years (2-8 years). In three cases some migration of the cup or signs of loosening were seen on radiographs. Recently, Schimmel and Slooff (1992, 1993) presented the results of this technique, when used in revision surgery, in a study of 83 revision hips in 77 patients with a mean follow-up of 5.3 years (2-10 years). Nine failures were found. Two hips became infected, radiographic loosening after full graft incorporation was seen in 3 hips, and in 4 hips incorporation failure was concluded according to the radiographic criteria used.

On the femoral side, bone stock loss is mainly seen in the intramedullary region and in the calcar area, often just leaving a thin sclerotic cortical wall. Several methods to deal with this problem have been described. The results of femoral revisions by simply filling the defects with bone cement were not satisfactory as discussed in the previous literature review. Even with modern cementing techniques it seems reasonable that adequate bone stock is required for satisfactory results (Wilson, 1987). Special designed stems have been described for cases with deficient calcar bone stock (Harris and Allen, 1981), or even custom-made prosthesis. Long stems which were distally cemented are used by Turner (1987). In a study of 165 hips, intra-operative complications were seen in 23 per cent of the procedures; mainly femoral perforations. After a mean follow-up of 6.7 year 12 per cent showed definite failure. Although it is concluded that cemented long-stem femoral components lower the mechanical failure rate, new problems are introduced. Given the fact that all prostheses will loosen sooner or later, probably the problems are transferred from the proximal femoral area to a more distal area. Wagner (1987) presented a femoral revision prosthesis with a long stem and a cementless anchorage of the conical component in the conically reamed femoral shaft. In cases of extensive damage to the cortical shaft, the prosthesis and the surrounding bone cement are removed by a transfemoral approach, longitudinally splitting the femur into halves. Initially, it was recommended to fill the gap between prosthesis and the two parts by cancellous bone grafts. However, vigorous bone regeneration was seen in the resorption defects, even without grafts (Wagner, 1989). Unfortunately, controlled follow-up studies of this technique are lacking. Grafting techniques, using different types of structural bone grafts, have been described for cases of severe femoral bone stock loss with additional loss of containment (Borja and Mnaymneh 1985, McGann et al. 1986, Head et al. 1987, Oakeshott et al. 1987, Allen et al. 1991). However, we think that, based on the experience with massive bone grafts in revisions on the acetabular side, massive and structural grafts should not be used (Mulroy and Harris 1990). This is confirmed by the problems reported recently with these massive allografts (Martin et al. 1993).

The clinical use of intramedullary femoral bone grafts has been described with cementless devices, although never in an impacted form and loaded by a stem (Tyer et al. 1987, Wagner 1987, Nelson et al. 1990). The incorporation of trabecular bone grafts, even when covered with bone cement, was shown in an animal model (Roffman et al. 1983).

In 1988 we developed a method to use impacted trabecular grafts on the femoral side. In this way an intramedullary reconstruction of the endosteal wall of the femur could be created by impacting morsellized allograft chips. By using this technique, a central prosthesis bed within the construction of grafts can be guaranteed. After the development of the technique an animal experiment was started. First, in an in vitro study in femora of the goat, the initial stability immediately after insertion was determined with both cemented and noncemented hydroxyapatite coated stems (Chapter 4). Next, in vivo tests were done in goats with both cemented and noncemented hydroxyapatite coated stems (Chapters 5 and 6). The clinical outcome, the radiological and biomechanical data and histological results were studied. Based on these experiments, in collaboration with the Princess Elizabeth Orthopaedic Hospital, Exeter, UK (Gie and Ling) and Howmedica International a Revision Instrument System (X-Change) was made for clinical use. The first clinical results from this revision system in 10 patients is presented in Chapter 7.

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CHAPTER 2

Effects of preparation techniques on the porosity of acrylic cements[1]

B. Willem Schreurs, Pieter T.J. Spierings, Rik Huiskes and
Tom J.J.H. Slooff

ABSTRACT - We investigated four acrylic cement preparation techniques for their effects on cement porosity: hand mixing, pressurization in a pneumatic pistol, centrifugation, and vacuum mixing. All the techniques were tested on three types of cement with different viscosity characteristics. The best results were obtained with vacuum mixing using a newly designed experimental system, yielding porosity reductions of 60-80 percent relative to hand mixing. Vacuum mixing with a commercial system was also effective, but to a somewhat lesser extent.
Pressurization and centrifugation had no substantial effect on the overall porosity. Centrifugation led to considerable nonuniformity in the distribution of pores and additives.

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INTRODUCTION

The porosity of acrylic cement is important for its fatigue strength and depends, among other things, on the preparation technique. We have determined the effects of four different techniques on the porosity of three cements with different viscosity characteristics in the curing phase.

MATERIAL AND METHODS

Cylindric test bars

Three different cement types were used: a low viscosity type (Zimmer LVC, Zimmer Inc., Warsaw, ID, U.S.A.), a medium one (Palacos EMD 42 521-Y), and a high viscosity type (Palacos R, Merck, Darmstadt, FRG.). In order to document the differences between these cements, their viscosity developments were measured in a Weissenberg Rheogoniometer, type R19 (Sangano Controls Ltd, U.K.). Using a rotating plate-cone configuration (Walters 1975), the simple shear viscosity as a function of time after mixing was determined (shear rate 0.36 s^{-1} and a mean room temperature of 22 °C). Although these viscosity vs. time curves are extremely sensitive to both the shear rate and the environmental temperature, objective comparisons could be made because all the test conditions were kept equal.

In the porosity tests, 26-mm-diameter cylindric cement bars were prepared. Means and standard deviations (SD) of the porosity values for the three cements, prepared in four different ways, were determined from the measured apparent density values, relative to the densities of the standard test bars. The reproducibility of the apparent density determination was 0.0015 g/cm^3 (approx. 0.12 percent), as determined from duplicate measurements, which is small relative to the variety found between test samples. During the tests the laboratory temperature was 24 ± 1 °C and the air humidity 30 ± 5 percent.

The different methods of cement preparation are illustrated in Figure 1. Hand mixing was carried out in a plastic bowl with a spatula, stirring frequency 1-2 rounds/s in accordance with the instructions of the manufacturer. After mixing, the cement dough was poured (LVC and Palacos E) or finger packed (Palacos R) into a cylindric mold.

In testing the pressurization pistol (Scientific Developments, Munich, FRG), mixing took place as in hand mixing, after which the cement dough was poured or finger packed (Palacos R) into the plastic pistol syringe and pressurized for 1 minute (high viscosity cement) to 3 minutes (low viscosity cement) at 8 bars air pressure in accordance with the instructions of

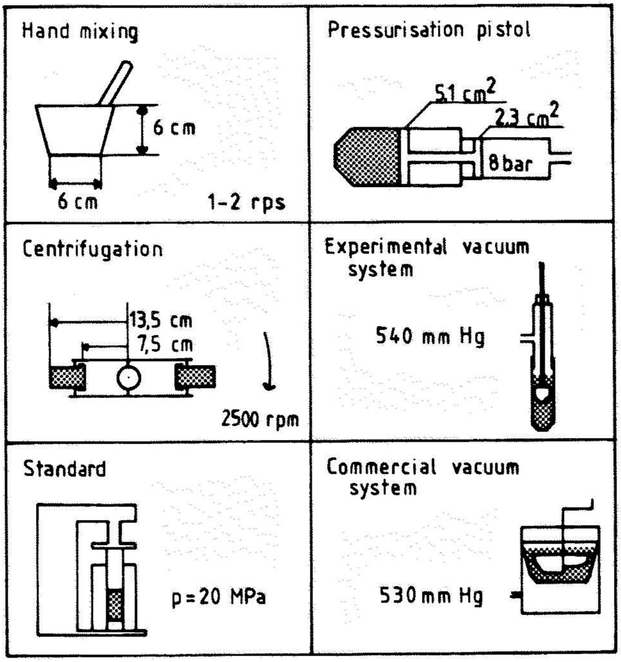

Figure 1. *Specifications for the hand-mixing method (upper left), pressurization pistol (upper right), centrifuge (middle left), experimental vacuum system (middle right), pressure curing for the reference bars (lower left), and the commercial vacuum system (lower right).*

the manufacturer. At the end of the pressurization period, the cement was left to polymerize.

Centrifugation was carried out, starting 80 seconds after normal mixing of the cement , in a Cemtrifuge ® (Biodynamic Technologies Inc., Pompano Beach, U.S.A.), at an angular velocity of 2.500 ± 50 rpm (strobe controlled), for 2 minutes, including 20 seconds' drag. The radius of the centrifuge was between 7.5 cm (top) and 13.5 cm (bottom). Cement mixing and syringe insertion were as in pressurization.

Vacuum mixing was performed first in a self-made apparatus. The design of this device was based on four requirements: 1) Powder and fluid are combined after a vacuum is applied; 2) stirring takes place in a vacuum; 3) the stirring rotor is removed in a vacuum; and 4) the cement dough is injected directly from the apparatus into the bone , or in this case, the test mold. The powder was put into a 26 mm plastic syringe, which was a part of the small Howmedica cement pistol. The fluid was poured into a glass bowl. Then , a vacuum of 540 (± 10)mm Hg was applied and the glass bowl was rotated to pour the liquid into the powder. Stirring was carried out with the rotor at 220 rpm for 45 seconds. Then, the rotor was pulled out , the vacuum was released 2 minutes after mixing started, and the cement was left to cure.

For the purpose of producing zero-porosity reference samples, standard test bars were made for each cement under pressure of 20 (± 2) MPa in a hydraulic press in the curing phase (15 min).

Stem fixation model

Tests were carried out with a mold simulating the curing conditions of cement around a femoral prosthesis (Figure 2). The purpose of this test was to determine whether porosity reductions, obtained during preparation, would be permanent after application of the cement in an artificial-joint fixation. In this case only the Palacos E cement was used, prepared by hand or by vacuum mixing.

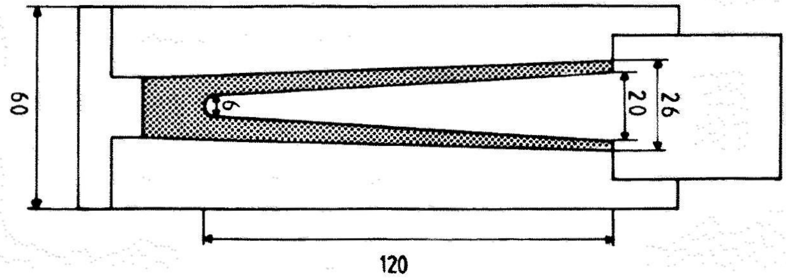

Figure 2. *The femur/stem mold for the simulation of stem fixation. The femur mold is made out of PTFE, the stem out of metal.*

In addition to the experimental vacuum device, the commercial Mixevac II ® (Stryker,U.S.A.) was used (Figure 1) according to the instructions of the manufacturer. In this case a vacuum of 508-559 mm Hg was applied after adding powder to the liquid, but before the mixture was stirred in a closed plastic stirring mill. This system was used both with and without the application of a vacuum in order to have a control for the use of the stirring mill alone. After stirring, the vacuum was released, the stirrer removed, and the cement poured into a syringe.

In all the cases the Howmedica syringe was used to fill the femur mold in the antegrade fashion. The metal stem was inserted 4 minutes after starting the mixing. The stem and the cement mantle were removed 15 minutes after insertion.

Porosity evaluation

All the test bars and cement mantles, for each technique and each cement, were produced five times except for the standard bars, which were produced twice. All of them were dehydrated for 10 (± 1) days in an exsiccator containing silica gel. After this period, the apparent density of each sample was determined using pycnometric methods according to ASTM 792-66 (Table 1). All the measurements were carried out in duplicate; ultrasound was used for removing air bubbles.

In addition, the test bars were radiographed. Then, two out of every five bars were sectioned using water cooling; the centrifugal specimens in four equal parts, and the others in three. The sections were polished, macroscopically checked, and evaluated for area porosity by quantitative microscopy (automatic gray discrimination of video image).

Table 1. *Density values of the standard reference samples, cured under 20 MPa pressure, as measured pycnometrically*

	Density (g/cm^3)	
Cement type	Sample I	Sample II
Zimmer LVC	1.242	1.243
Palacos E	1.293	1.289
Palacos R	1.290	1.290

RESULTS

Cylindric test bars

Due to its high viscosity, vacuum mixing of Palacos R cement proved impossible because of the stirring methods, both in the experimental and in the commercial system (Figure 3).

Centrifugation of LVC cement created a thin liquid layer on top of the test bar, curing eventually into a foam-like matter. The centrifuged Palacos E samples showed a white layer on the other side, close to the bottom, which was on the far side of the centrifugation axis. This material turned out to be the radiopaque filler zirconium oxide.

Microscopic evaluation of the standard reference test bars, produced under high pressure, showed a porosity of less than 0.1 percent in all the cases, indicating that the requirement of zero porosity was nearly fulfilled (Table 1).

Porosity reductions relative to hand mixing were only obtained with the vacuum method (Table 2, page 26). However, the centrifuge seemed to have some effect with Palacos E cement and the pressurization pistol with Palacos R cement. In all the cases, the Palacos E cement had lower porosity than LVC and Palacos R.

The radiographs displayed macroscopically visible pores for all three cements prepared by hand mixing and by the pressurization pistol technique. In centrifuged samples of LVC and Palacos E, no pores were visible in contrast to Palacos R. The centrifuged LVC samples showed a cloudy density near to the bottom, on the far side of the centrifugation axis (Figure 4); and the centrifuged Palacos E samples showed a dense layer at the far end. The radiographs of the vacuum mixed LVC and Palacos E samples showed macroscopic pores only occasionally near the top.

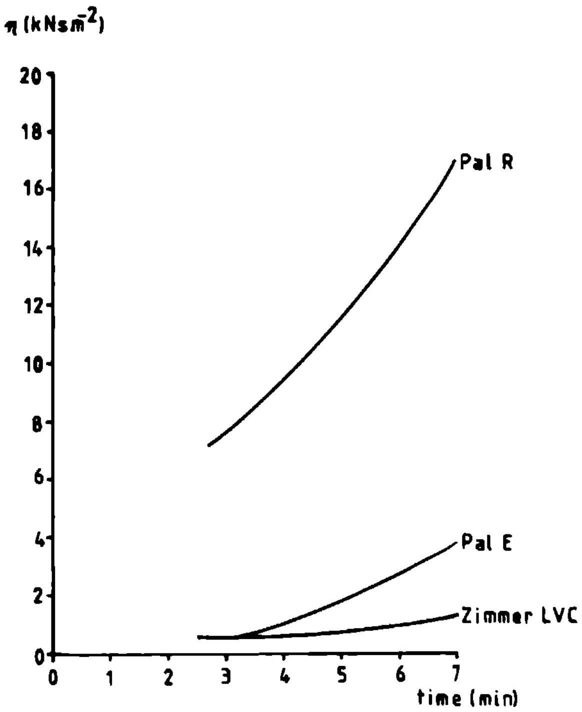

Figure 3. *Viscosity developments as function of time after start (hand) mixing for Palacos R, Palacos E-Y, and Zimmer LVC. Average of five tests in a plate/cone configuration of a rotating rheogoniometer (room temperature 21.6-22.7 °C; shear rate 0.36s^{-1}).*

Macroscopic inspection and measurement of the polished cross sections of the test bars revealed pores of 0.5 to 6.0 mm diameter for all three cement types after hand mixing and pressurization with the pistol. The largest pores, up to 6 mm, were found in the hand-mixed Palacos R. The centrifuged samples of the LVC and Palacos E cement showed no pores larger than 0.5 mm; some were visible, however, in the Palacos R samples (up to 1 mm). Macroscopic pores in the vacuum-mixed samples were seen only incidentally.

Under the microscope, pores were seen in all cross sections of all the samples except for the standard bars (Figure 5). These results for Palacos E confirm those of the apparent density determinations, but in this case the standard deviations were much higher (Table 2, page 26).

A notable finding was that in the centrifuged samples of all three cements the porosity in the bottom section (on the far end of the centrifugation axis) was the smallest, and in the top section the largest (Figure 5). The LVC samples showed the highest gradient in this respect (bottom 3 percent, top 16 percent). The average diameter of all the pores larger than 60 micrometer in the cross sections was estimated microscopically (Table 3, page 26).

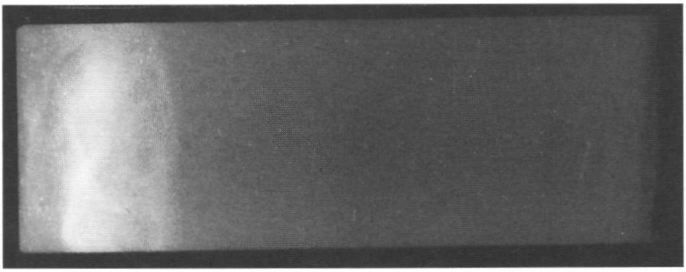

Figure 4. *Radiograph of a centrifuged LVC cylinder. Bottom to the left.*

Stem fixation

The porosity reduction of vacuum mixing had a permanent character also after application of the cement in prosthetic fixation (Table 4, page 26). Some general reduction in porosity occurred when comparing the cement mantle with the test bars. This may be an effect of superior heat conduction from the cement mantle, with less monomer boiling as a result or of porosity reductions during flow through the nozzle of the syringe. The commercial vacuum system, although to a somewhat lesser extent, had an effect similar to the experimental system on cement porosity.

Table 2. *Volume percentage porosity (mean (SD)) in the cylindric specimens, calculated from the apparent density measurements of the tests samples* as determined with microscopic porosity measurements*

<table>
<tr><th rowspan="3">Cement Type</th><th colspan="5">Porosity (%)/Preparation Method</th></tr>
<tr><th rowspan="2">Hand-mixed</th><th rowspan="2">Pressurization pistol</th><th colspan="2">Centrifuge</th><th rowspan="2">Experimental vacuum system</th></tr>
<tr><th>Bottom</th><th>Top</th></tr>
<tr><td>Zimmer LVC</td><td>7.7 (0.7)</td><td>6.8 (1.2)</td><td colspan="2">9.3 (1.4)</td><td>1.2 (0.1)</td></tr>
<tr><td>Palacos E</td><td>4.2 (0.4)</td><td>4.3 (0.3)</td><td colspan="2">3.2 (0.4)</td><td>0.9 (0.2)</td></tr>
<tr><td>*Palacos E</td><td>5.1 (3.3)</td><td>5.5 (3.5)</td><td>3.4 (1.2)</td><td>4.4 (1.8)</td><td>0.3 (0.5)</td></tr>
<tr><td>Palacos R</td><td>8.4 (1.1)</td><td>6.6 (1.1)</td><td colspan="2">6.9 (0.6)</td><td>-</td></tr>
</table>

Table 3. *Average por size for pores > 60 μm in the cross sections of the test samples, as estimated microscopically*

<table>
<tr><th rowspan="3">Cement Type</th><th colspan="5">Average pore size (mm)/Preparation Method</th></tr>
<tr><th rowspan="2">Hand-mixed</th><th rowspan="2">Pressurization pistol</th><th colspan="2">Centrifuge</th><th rowspan="2">Experimental vacuum system</th></tr>
<tr><th>Bottom</th><th>Top</th></tr>
<tr><td>Zimmer LVC</td><td>0.22</td><td>0.20</td><td>0.16</td><td>0.30</td><td>0.17</td></tr>
<tr><td>Palacos E</td><td>0.18</td><td>0.21</td><td>0.14</td><td>0.18</td><td>0.10</td></tr>
<tr><td>Palacos R</td><td>0.25</td><td>0.25</td><td>0.25</td><td>0.31</td><td>-</td></tr>
</table>

Table 4. *Volume percentage porosity (mean (SD)), as calculated from the apparent density measurements, in the tests samples and in the cement mantle, simulating femoral stem fixation (Palacos E)*

<table>
<tr><th rowspan="3">Test configuration</th><th colspan="4">Porosity %/Preparation Method</th></tr>
<tr><th rowspan="2">Hand-mixed</th><th rowspan="2">Experimental vacuum system</th><th colspan="2">Commercial vacuum system</th></tr>
<tr><th>with vacuum</th><th>without vacuum</th></tr>
<tr><td>Cylindric bars</td><td>4.2 (0.4)</td><td>0.9 (0.2)</td><td>-</td><td>-</td></tr>
<tr><td>Stem fixation model</td><td>2.6 (0.6)</td><td>0.7 (0.1)</td><td>1.3 (0.3)</td><td>3.0 (0.5)</td></tr>
</table>

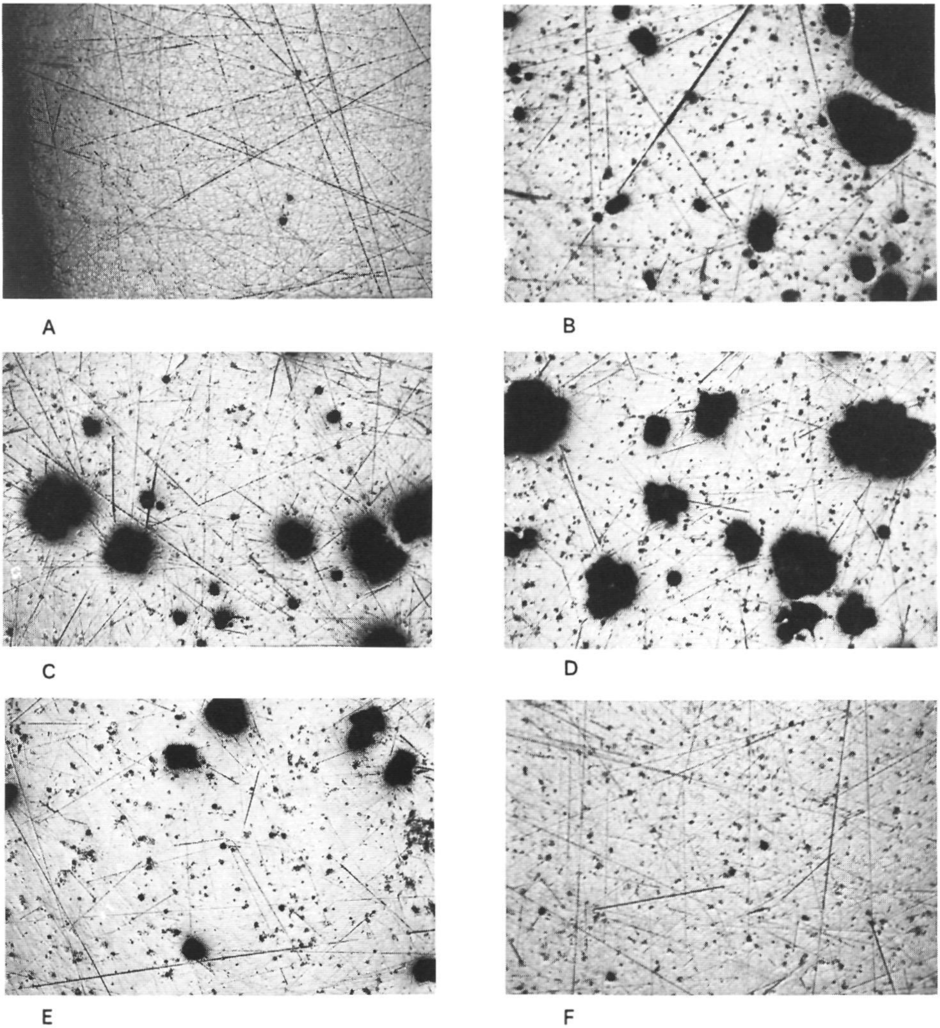

Figure 5. *Photomicrographs of the cross sections of the Palacos E test samples (X 57). A. Standard reference. B. Hand-mixed. C. Pistol. D. Centrifuged (top). E. Centrifuged (bottom). F. Vacuum-mixed.*

DISCUSSION

According to de Wijn (1982), pores in acrylic cement can be caused by either of three mechanisms: by air solutions in the monomer liquid, by entrapment of air in the cement dough during stirring, and by boiling of monomer. Debrunner (1976) showed that microscopically visible pores smaller than 60 micrometer in diameter are abundant, but do not contribute substantially to the overall porosity. Bayne et al. (1975) achieved a reduction in the porosity of cement when using high pressure in curing. The pressures did not affect the polymer chain length, so it may be assumed that our standard test bars, also cured under pressure, are valid references for porosity.

The porosity values found by us in the hand-mixed samples are close to earlier results reported in the literature; Keller and Lautenschlager (1983) found a 6.4 percent average porosity in LVC cement, and Jasty et al. (1985) found a 9 percent average porosity in Palacos R cement. Gates et al. (1983) introduced the centrifugation technique for reducing the porosity and increasing the strength of acrylic cements. Burke et al. (1984), from the same group, found an increase in static and fatigue strength in Simplex P specimens after centrifugation. Jasty et al. (1985) found definite effects of centrifugation on the porosity in AKZ and Simplex P cements, but not in Palacos R and Zimmer LVC cements. The latter findings were confirmed by Rimnac and Wright (1985), who reported that centrifugation had no effect on the fracture toughness of Palacos R and Zimmer LVC cements.

A general problem when comparing results of cement centrifugation is that the angular velocities and centrifugation times are variable, and that centrifuge radii are seldom reported. It also appears from the literature that the effects of preparation techniques vary among cements, predominantly depending on the viscosity vs. time characteristics. Hence, documentation of these characteristics is of importance (Figure 3). The three cements tested by us are believed to reasonably represent the variation in cement types that are available.

Our findings relative to the centrifugation of Palacos R cement are in general agreement with those of Jasty et al. (1985). They did not, however, report the increased porosity of Zimmer LVC cement that we found, probably because of the less dependable cross-sectional microscopic evaluation technique that was applied in their measurements. This increase in our tests was mainly an effect of local monomer boiling and foaming.

Skinner and Murray (1985) reported the effects of centrifugation on the apparent density distribution in the cement, whereby the radiopaque fillers in particular are forced away from the centrifugation axis, through the cement dough, and the pores remain concentrated on the other side. We found separation of radiopaque fillers with Zimmer LVC and Palacos E.

Because pores of macroscopic size were not found in the radiographs of the centrifuged samples, in contrast to the hand-mixed samples, and because the overall porosity of the centrifuged samples was not reduced, it must be assumed that this technique divided the larger pores into smaller ones. The gradient in the average pore size over the length of the cylindric bars can be explained by the nonuniform distribution of the centrifugation forces. It is probably due to the higher viscosity of Palacos R that this mechanism occurs to a lesser extent in this case.

The pressurization pistol is assumed to reduce the sizes of the pores in the cement. Because the viscosity of the cements increases during the pressurization period, the reduced pore sizes would be permanent (Dreanert 1986). It is important to note that due to an area increase of 225 percent, the real pressure on the cement is only 3.5 bars when the air pressure is 8 bars.

Keller and Lautenschlager (1983) and Eyerer and Jin (1986) reported that an increased cement porosity resulted in lower tensile strength. The former authors found an increase of strength when using the cement pistol without prepressurization. These results may be explained by the effects of the small nozzle of the pistol (3.5 mm diameter), which may cause a redistribution of the pores while the cement is flowing out.

We found here that the use of the cement pistol had no effect on the pore sizes in either of the three cements, whereas the overall porosity did not change in Palacos E and Zimmer LVC, and it was reduced only slightly in Palacos R.

Vacuum mixing resulted in substantial reductions of the overall porosity and average pore sizes in both Palacos E and Zimmer LVC cements. Unfortunately, it could not be applied to Palacos R, due to its high viscosity.

Demarest et al. (1983) mixed Simplex P cement under 730 mm Hg vacuum and obtained an average porosity reduction from 5 percent to 1 percent, and a clear increase in strength. Lidgren et al. (1984) compared the effects of 570 mm Hg vacuum mixing on an high and a low viscosity cement. They found that the results of the high viscosity cement were most dramatic, amounting to a strength increase of 15-20 percent. Later, Lidgren et al. (1987) compared the fracture strength, stiffness, hardness, fatigue life, and porosity of hand- and vacuum-mixed Palacos cement kept at 4 °C. They found substantial improvements of mechanical properties and a reduction of the porosity for the vacuum method. Wixson et al. (1985) obtained a porosity of 0.1 percent in vacuum-mixed Simplex P, as measured microscopically in cross sections.

Simulating the application of cement in hip-prosthetic fixation, we found that the porosity reduction obtained in vacuum mixing was permanent. The overall porosity in the actual cement mantle was even less than in the test samples, probably as an effect of the lower curing temperature, or due to flow in the nozzle of the syringe (Keller and Lautenschlager 1983)

The use of both the experimental and the commercial vacuum system resulted in porosity reductions, but to a much higher degree in the experimental system. This was caused by creating a vacuum before the powder and the fluid were combined, and by pressing the dough directly out of the cartridge after mixing.

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CHAPTER 3

The effect of the extracorporeal shock wave lithotriptor on bone cement[1]

B.W. Schreurs+, A.F. Bierkens*, R. Huiskes+, A.J.M. Hendrikx*, T.J.J.H. Slooff+

ABSTRACT - For the purpose of studying its applicability for acrylic cement removal during total hip revision surgery, experiments with an extracorporeal shock wave lithotriptor were carried out. High energy shock waves (HESW) were focussed on discs of polymethylmethacrylate bone cement. The average discharge was 18.1 kV; the number of shock waves 0, 100, 250, 500, 1000 and 2000; the application rate was 85 shocks every minute. Macroscopic or radiographic effects were not in evidence. Microscopically, typical lesions in a small concentric focal area with a diameter of 8.5 (± 2.5) mm were found. The individual lesions were smaller than 0.1 mm, and displayed characteristic shapes. The area porosity increased with the number of shocks. The maximal area porosity caused by the HESW, measured by quantitative microscopy, was 4 percent after 2000 shock waves. The lesions were also studied by scanning electron microscopy. It can be concluded that HESW causes only microscopical lesions on the frontal surface of discs of bone cement, and that these lesions are small compared to the pores normally present in bone cement, when applied clinically.

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+Institute of Orthopaedics; *Department of Urology

INTRODUCTION

Polymethylmethacrylate is used as a grouting material to locate and fix total hip arthroplasties in the bony cavity. After ten years about ten percent of the arthroplasties need revision (Ahnfelt et al.,1990). The absolute number of revisions is increasing, because total hip replacement is now a widely used procedure. Removal of bone cement is a meticulous process, associated with many complications. Several methods have been described to facilitate removal (Slooff and Lindner 1974, Eftekhar 1977, Harris and Oh 1978, Nieder et al. 1979, Beacon et al. 1979). Recently, extracorporeal shock wave lithotripsy was proposed for this purpose (Karpman et al. 1987, Weinstein et al. 1988). The purpose of this project was to obtain information about the effect of high energy shock waves (HESW) on acrylic cement.

MATERIALS AND METHODS

Sulfix-6 (Manufacturer: Sulzer, Winterthur, Switzerland) bone cement was used. Cement preparation was carried out in a plastic bowl with a spatula, according to the instructions of the manufacturer. The stirring frequency was 1-2 rounds/sec, the room temperature 21 (± 1) degrees Celsius. After mixing, the cement was poured into a cylindrical mold. In this way two 26 mm diameter cylindrical cement bars were prepared. One bar was left to cure under atmospheric circumstances, the other bar was set under pressure of 20 (± 2) MPa in a hydraulic press during the curing phase (15 minutes).

The bars were then sectioned into discs of 2.5 (± 0.2) mm, using water cooling. The sections were polished, checked macroscopically and radiographically, and evaluated for area porosity by quantitative microscopy (automatic gray discrimination of video images). These measurements were performed in two rectangular directions across the polished side.

The discs were placed in a water bath, with a temperature of 37.5 (± 1.5) degrees Celsius. The experiment was performed with a Siemens Lithostar lithotriptor. The high energy shock waves were orientated perpendicular to the polished disc area. The target location was selected using a two directional radiographic image identification system. The average discharge was 18.1 kV, the number of shock waves on the different slices 0, 100, 250, 500, 1000, and 2000. The application rate was 85 shocks every minute, the standard rate of the device used. Thereafter the discs were checked macroscopically, radiographically, and again evaluated for area porosity. Some slices were sputter-coated with gold and examined by scanning electron microscopy (SEM).

In order to determine an optimal and reproducible experimental set-up, the pressure at different sites of the focus of the lithotriptor was measured (Oosterhof et al. 1989). The pressure measurements were performed using a piezoelectrical crystal transducer (Imotec) connected with a 100 mHz oscilloscope (Gould DSO, 4072). Pressures at different kilovoltages (kV) were registrated and a field of relative pressures around the focus was determined by positioning the transducer at different sites. These measurements revealed that the site of the maximum pressure was not identical with the radiological focus, but located 10 mm away from the shock-wave tube along the axis of the focus (fig 1a/1b). Considerably elevated pressure could still be measured several centimeters away from the radiological focus, while in the lateral plane the pressure rapidly decreased 2-4 mm away from the radiological focus. The pressures depended largely on the voltage (kV) discharge applied, in a somewhat regressive way. These pressure measurements indicate that it is incorrect to define a focus; it is better to speak of a focal area. The Lithostar creates pressures in a cigar-like focal area.

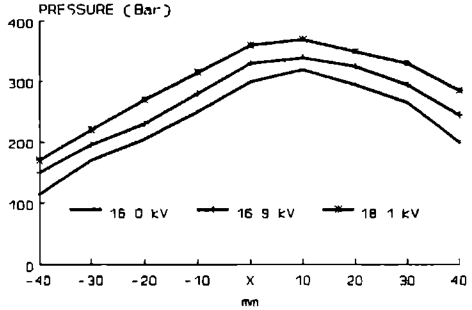

Figure 1a. Pressures in the central axis of the focal area at different distances (in mm) from the radiological focus X at different kV discharges.

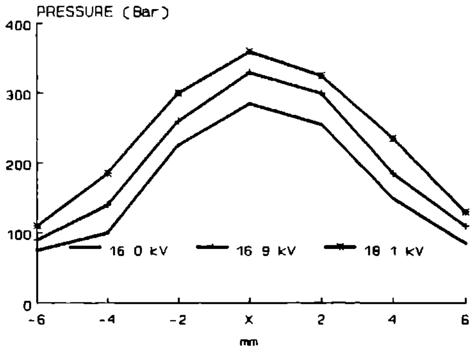

Figure 1b. Pressures lateral to the central axis of the focal area at different distances (in mm) from the radiological focus X at different kV discharges.

RESULTS

Macroscopically and radiologically, pores were visible on the slices cured under atmospheric pressure; the slices of the bars cured under high pressure showed no pores. The microscopically estimated area porosity revealed significantly different results between the discs cured under atmospheric pressure and those cured under high pressure (table 1).

Table 1. *The Effect of the Extracorporeal Shock Wave Lithotriptor on Bone Cement: Area Porosity estimated of Total Disc Surface, Sulfix-6*

	Cured under Atmospheric Pressure		Cured under 20 MPa Pressure	
Number of shots	Before	After ESWL	Before	After ESWL
0	1.8 (1.6)	1.7 (1.6)	0.4 (0.2)	0.4 (0.2)
100	1.8 (2.0)	2.8 (3.0)	0.5 (0.5)	0.6 (0.4)
250	1.5 (1.6)	1.6 (1.2)	0.8 (0.3)	0.8 (0.5)
500	1.4 (1.7)	2.4 (1.9)	0.4 (0.2)	0.6 (0.4)
1000	1.7 (2.2)	2.6 (3.1)	-	0.5 (0.4)
2000	1.1 (1.7)	2.2 (3.1)	-	0.7 (0.7)

After the application of the shock waves, no macroscopical or radiographical changes were visible. Microscopically, no changes in the overall percentage of estimated area porosity could be found (table 1). However, in all cases typical lesions were visible microscopically in a concentric area around the focal center (fig. 2 a/b). The diameter of this area was 8.5 (± 2.5) mm. No correlation between the diameter of this area and the number of shots was apparent. The average size of the larger lesions in the center of the focal area, measured microscopically, was 0.07 (± 0.01) mm. The distribution of the area porosity around the focal center was measured in the cases of the discs cured under pressure (fig. 3, page 36). The size of the lesions made by the HESW were small compared to the pores occurring in the discs cured under atmospheric pressure. Incidental cracks of the rim of a pore were seen, when this pore had been in the center of the focal area. Sem of the typical lesions showed a more or less complete circular damage, with a relatively unimpaired central part (fig. 4, page 36)

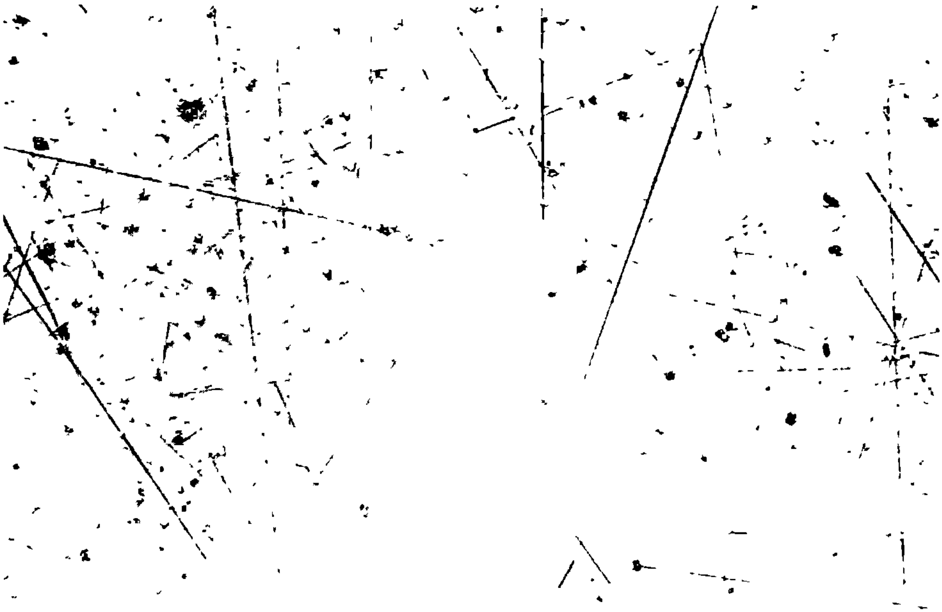

Figure 2a. Microscopic view of disc before HESW. Magnification factor 30.

Figure 2b. Typical lesions seen in the focal area after 2000 shock waves. Magnification X30

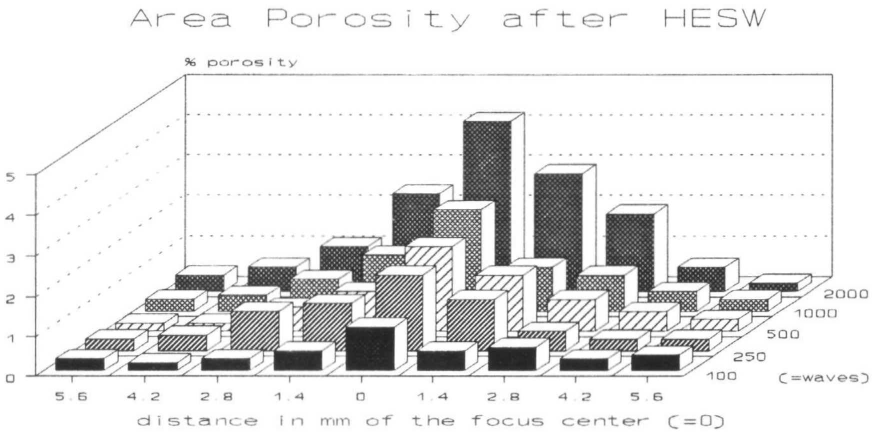

Figure 3. *Area porosity in the focal center of high pressure bars estimated with automatic gray discrimination of video images.*

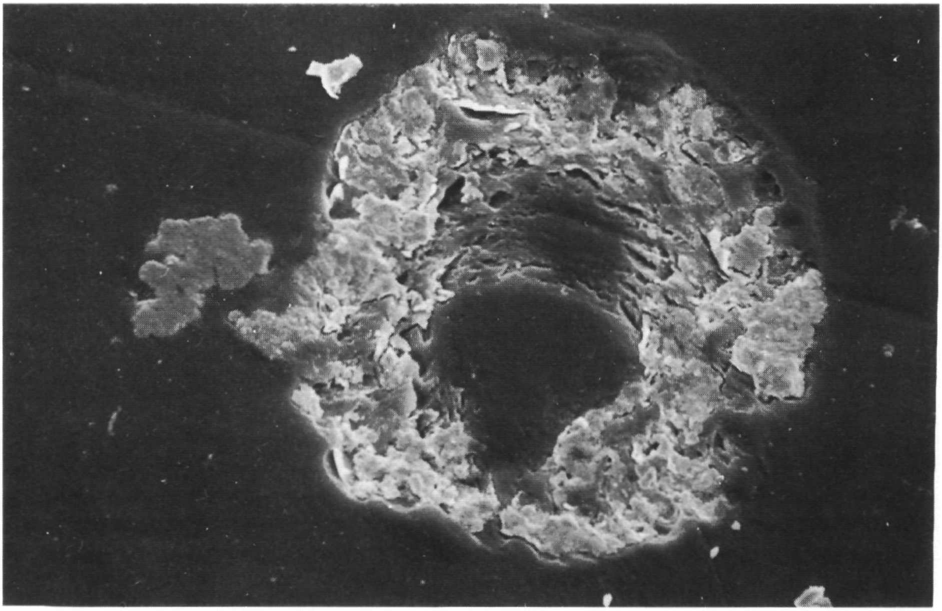

Figure 4. Scanning electron microscopy of typical defects. Magnification factor 1200.

DISCUSSION

The extracorporeal shock wave lithotriptor was introduced in medicine in the late seventies (Chaussy et al. 1980). By generating HESW it is possible to disintegrate kidney-stones in a contact-free and non-invasive way. Karpman et al. (1987) introduced high energy shock waves generated by a lithotriptor as a technique which might be utilized in orthopaedics to facilitate the removal of the femoral prosthetic component and bone cement out of the femoral canal. Experiments were done with 3 canine femurs containing stainless steel rods fixed with bone cement. The area treated with HESW showed many microfractures of the bone cement and a disruption of the cement/bone interface, as was established by reflected light and scanning electron microscopy. Weinstein et al (1988) also used canine femora. After treatment, the bones were sectioned transversely, and mechanical push-out tests were performed. Results indicated that HESW does have a loosening effect. The bone-cement interface was inspected with scanning electron microscopy; microfractures, loose-bodies, and widening was seen, with few lesions of the surrounding bone.

The goal of this study was to obtain information about the effect of HESW on bone cement. The shock waves can be generated in different ways. In the Siemens Lithostar this is done by large-surface, electromagnetic pressure transducers. Shocks waves are focussed by means of an acoustical lens. The shock wave is composed of low and high frequencies.

The intensity of treatment can be varied by two parameters, the discharge voltage and the number of shocks. It seems that a relative increase in head voltage is more effective then a relative increase in the number of shocks (Whelan and Finlayson 1988). In this study only the number of shocks was varied, discharge voltage was chosen as submaximal for the device used.

After being evoked, the shock waves are conducted to the body by a water-containing medium. Water is chosen because its acoustic impedance is similar to that of soft tissue and cancellous bone (Weinstein et al. 1988). Hence excitation of a disc of bone cement in a water bath can be considered as a simplified model for the excitation of the cancellous bone-cement interface. High energy shock waves can travel through two or more substances without dissipating a significant portion of energy if there is no change in acoustic impedances. Energy transfer will mainly occur at the interface of media which have different impedances. When a shock wave hits the frontal surface of a stone, it will be separated into two directions according to the acoustic impedance (Whelan and Finlayson 1988, Kambe et al. 1988). A part of the shock wave will be reflected, the other part will enter the stone. This latter part is transmitted through the stone with a very high pressure front. If this pressure exceeds the compressive strength of the stone, it will disintegrate. On the opposite side of the stone, at the stone-water interface, the reflecting waves produce negative pressure waves in the stone. As a result, a highly elevated positive pressure front passes through the stone, followed by a negative pressure front very close to the interface. This pressure wave causes tensile stress, whereby the stone can be broken. Because the tensile strength of a stone is usually much smaller than the compressive strength, this mode appears to be the most dominant one.

It has been described, that shock waves generated by HESW can cause violent acoustic cavitations in water (Coleman et al. 1987, Kambe et al. 1988). When these cavitations collapse near a boundary, they can cause significant damage in two ways. First, during the cavitation collapse a very rapid liquid jet evolves, which can impact the nearby boundary. Secondly, after the jet has penetrated the cavitation, a toroidal ring of vapour is generated, which eventually also collapses and causes damage. These effects will be mainly seen on the frontal surfaces of the materials concerned.

The effect of the HESW on bone cement discs were visible microscopically, and the lesions were small compared to the pores normally present. No disintegration of the discs was seen, indicating that the tensile and compressive stresses generated were not strong enough to cause breakage. Microfractures were only seen in relation with a pore in the focal area, indicating that these pores probably act as stress risers. Because the pores disturb the measurements of the area porosity caused by the HESW, a bar cured under high pressure was used as well. Discs of such bars do have a very low porosity, as was established in a previous study (Schreurs et al. 1988, see chapter 2). The typical lesions seen on the frontal surfaces of the discs were probably caused by cavitational effects, which may explain their typical form.

There was no difference in area porosity when measured over the total disc surface. This can be explained by the fact that the focal area amounted to only about 16 percent of the total disc surface.

Discs were placed in the radiological focus of the lithotriptor, although there is a discrepancy between the radiological and the pressure focus. At 18.1 kV discharge voltage the influence of this discrepancy on pressure height is small.

The conclusion is that HESW causes microscopic lesions in a small area on the frontal surfaces of cement discs. The lesions are small relative to the pores usually present in bone cement. The lesions increase in magnitude proportionally with the number of shock waves. However, pores in bone cement, present after in vivo application, may behave as stress risers and initiate cracks secondary to HESW. Moreover, in the clinical situation bone cement may be mixed with blood and grease, and the interface of bone cement and cancellous bone will be structurally complex. The effect of HESW on this interface needs further investigation.

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CHAPTER 4

The initial stability of cemented and noncemented femoral stems fixated with a bone grafting technique[1]

B. W. Schreurs, R. Huiskes, and T.J.J.H Slooff

ABSTRACT - To reconstruct intramedullary bone stock in revision surgery of failed total hip arthroplasties a method was developed using impacted trabecular bone grafts. In an in vitro model with femora of the goat, the initial stabilities of both cemented and noncemented hydroxyapatite coated stems in this graft construction were determined in a loading experiment immediately after insertion. Displacements of stems relative to bone were determined with rontgen-stereophotogrammatic analysis. The most important movements were axial rotations (cemented stems up to 2.1 degrees, noncemented stems up to 6.8 degrees), and subsidence (cemented stems up to 0.5 mm, noncemented stems up to 2.9 mm). These motions were caused predominantly by slippage and compaction of grafts. It is concluded that the cemented stems reach a better initial stability, probably by cement penetrating in the graft layer. For noncemented stems used in combination with the grafting technique developed, additional means to guarantee initial stability are needed.

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INTRODUCTION

Although results of total hip arthroplasties are impressive, the number of revisions is growing. Generally speaking, about 10 percent of the arthroplasties must be revised within 10 years postoperatively. The main reasons for revision are aseptic loosening and infection (Ahnfelt et al. 1990). Problems on the femoral side, often encountered, are the loss of bone stock and sclerosis of the endosteal wall. The bone stock loss is caused by the loosening process itself and by the removal of bone cement during these revisions (Slooff and Lindner 1974, Eftekhar 1977, Harris and Oh 1978).

Several grafting techniques, with different types of bone grafts, have been described for cases of severe femoral bone loss (McGann et al. 1986, Head et al. 1987, Oakeshott et al. 1987, Borja and Mnaymneh 1985, Wagner 1987). In our department, bone grafting techniques are successfully used in severe cases of acetabular bone loss (Slooff et al. 1984). After cleaning and reaming, trabecular bone chips are impacted to reconstruct the acetabulum. A cemented cup is then implanted. In 1988 we developed a method to use a similar technique for the femoral side. Using special equipment, an intramedullary reconstruction of the endosteal wall is created with bone grafts. Within this reconstruction a stem is fixed.

An in vitro study was carried out to determine the immediate post-operative relative motions of stems under loading fixated with this grafting technique, using Roentgen-stereophotogrammatic Analysis (RSA) according to Selvik (1974). Revisions of failed THA are performed by cemented and noncemented techniques. Hence, both cemented and non-cemented stems were investigated.

MATERIALS AND METHODS

Eight freshly frozen goat femora were used in combination with freshly frozen trabecular bone grafts of sternal origin. The maximal storage period, at -20 degrees Celsius, was six months. After thawing, the femoral head was resected using an oscillating saw. Next the femoral canal was opened using hand reamers (diameter 8-13 mm). The femur of the goat contains trabecular bone only in the proximal part. With the reamers only this trabecular bone in the proximal femur was removed; next canal lavage was performed. Then an appropriately sized AlloPro bone cement plug was screwed on a metal rod (cemented stems rod diameter 8 or 10 mm, noncemented stems rod diameter 10 mm).

This construction was introduced in the medullary canal. The space between this rod and the cortical bone (2-4 mm) was filled with grafts in a retrograde fashion. The trabecular bone grafts were chip-like and obtained from the sternum by using rongeurs. By using a specially developed set of instruments, the grafts were impacted (fig. 1). In this way, an intramedullary wall of bone chips was created. After completion of the filling process, the central metal rod was unscrewed and removed, leaving a central cavity surrounded by bone grafts. Within this central cavity a stem was inserted.

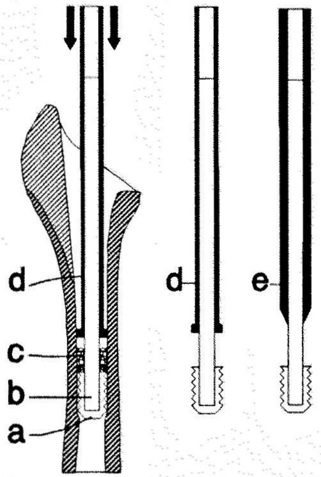

Fig. 1 Schematic drawing of the graft impaction technique by using a special set of instruments. A bone cement plug (a) is screwed on a metal rod (b) and introduced into the canal. The space between this metal rod and the cortical bone is filled with trabecular bone grafts (c). These grafts are impacted using metal tubes sliding over the central rod. Different types of tubes are used for axial (d) and radial (e) impaction of the grafts.

In four cases, cemented prostheses were placed (Mathys type 2.30.702, fig 2a). Bone cement (Sulfix) was injected in retrograde fashion by using a cement syringe, 225 (± 15) seconds after adding the monomere to the powder, at a room temperature of 22.5 (± 1.5) degrees Celsius. The prosthesis was placed 285 (± 15) seconds after starting the mixing process.

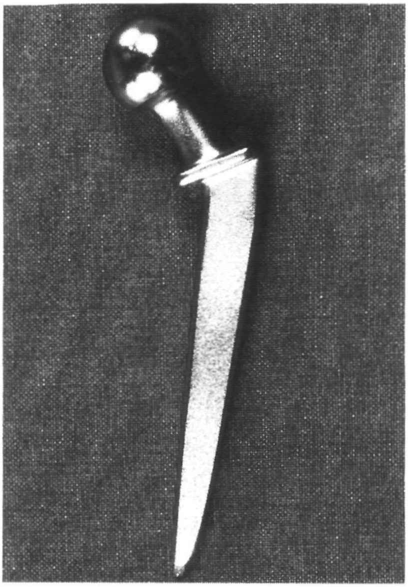

Fig. 2a The prosthesis used in combination with bone cement.

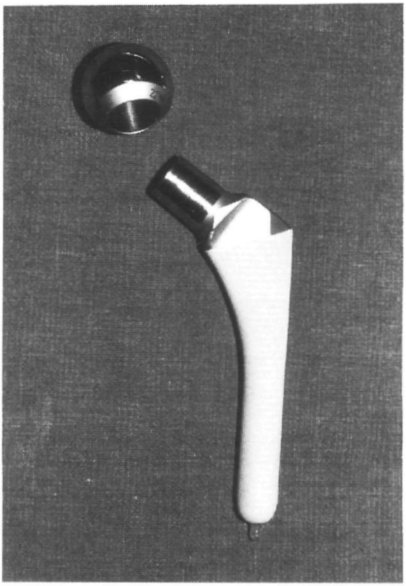

Fig. 2b The hydroxyapatite coated titanium prosthesis.

In the other four femora, noncemented titanium prostheses, fully coated with hydroxyapatite (thickness 40-60 micrometer), were inserted following the normal clinical procedures (fig 2b). The prosthesis was manufactured by Osteonics, and the coating was applied by CAM b.v. (de Groot et al. 1987)

Both types of prostheses had a tantalum pellet attached to the tip prior to insertion, contained in an acrylic strut, glued to the metal.

The bones were wrapped in physiological saline-drenched gauze bandages and kept for 24 hours at 4 degrees Celsius. They were then resected just above the distal condyles and partly embedded in PMMA. Tantalum pellets were attached proximally and distally to the medial and lateral sides of the cortical bone. At each location 3 pellets were placed. Hence, four sets of three pellets defined the position of the bone (fig. 3). Two small PMMA rods, containing three tantalum pellets each, were glued to the medial and lateral aspects of the lower neck of the prostheses. Hence, two sets of three pellets proximally and one single pellet distally defined the position of the prosthesis (fig. 3)

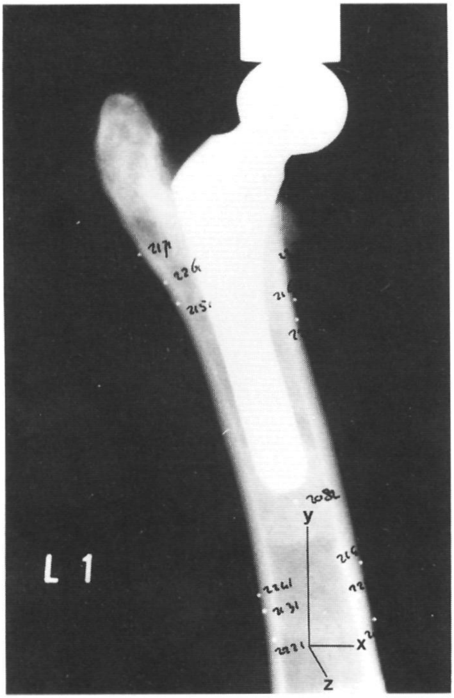

Fig. 3 Femur with bone grafts and a HA-coated prosthesis. The laboratory coordinate system is shown.

The implanted prostheses were then loaded in an MTS-testing machine. Relative to the vertical position, the femora were tilted 15 degrees in the lateral direction and endorotated 45 degrees, in order to obtain a physiological load on the femoral head (Bergmann et al. 1984). The load was applied stepwise from zero to 200, 500, 800 (± 10) N. After each loading step, the load was kept constant for 10 minutes (fig. 4). Before loading, one and ten minutes after each load was applied, and again 10 minutes after final unloading, stereorontgenograms were taken (fig. 4). These were measured on an Aristomat digitizer, and the 3-D pellet positions at all selected time periods during the loading cycle were determined with the RSA computer system. To increase the accuracy of the results, all roentgen films were measured 5 times and the results averaged. Using the second part of the RSA computer system, based on rigid body kinematics, and the subsequent pellet-position data, the three-dimensional displacements of the prosthesis relative to the bone were evaluated (Selvik, 1974). This evaluation produced relative translations along the x-axis (lateral-medial translation), y-axis (axial translation, i.e. subsidence) and z-axis (anterior-posterior translation) of a particular base point of the prosthesis, and rotations about the x-axis (rotation in the sagittal plane), y-axis (horizontal plane) and z-axis (frontal plane). The coordinate axes are depicted in fig. 3. In order to obtain a good assessment of the relative displacements, the translations were calculated for three base points in the prosthesis, one the pellet under the distal tip, and the other two pellets at the medial and lateral proximal sets. In order to neutralize the effects of bone deformations due to loading (i.e. bending), all the results were evaluated using four different combinations of the four bone-pellet sets.

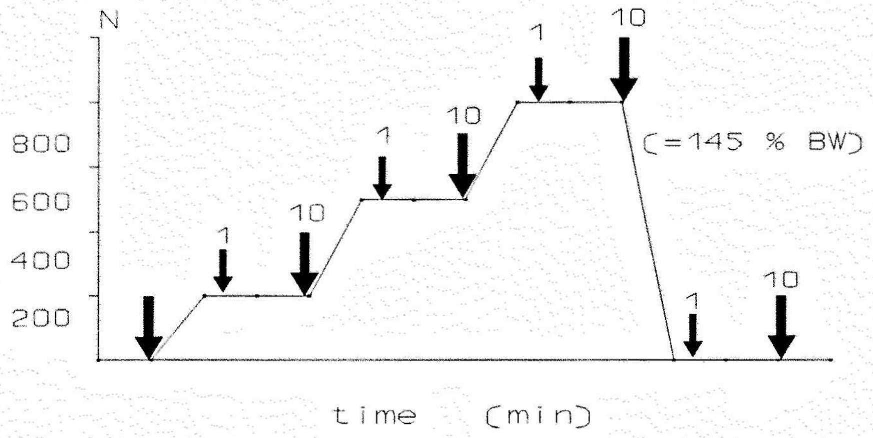

Fig. 4 The loading regime. Roentgenostereograms were made 1 and 10 minutes after each step in load. The arrows indicate when roentgenstereograms were taken.

RESULTS

The standard deviation for the translations was estimated at 0.036 mm and for the rotations at 0.07 degree, as determined by 5 independent measurements. The influence of the bone pellet-set combination selected was negligible. Only in the case of prosthesis CEM-4 the deviation between the rotations determined with the different combinations of pellets was larger (0.1 degrees) than the standard deviation.

In all loading steps very little difference was found for the displacements after 1 and 10 minutes. In the presentation of results we limit ourselves to the displacements determined after 10 minutes.

In both the cemented and the noncemented cases, the rotations around the medial-lateral x-axis in the sagittal plane, and the antero-posterior z-axis in the frontal plane were small (between -0.5 and 0.4 degrees), except in one case (HAP-4, a frontal-plane rotation of 2.3 degrees). In both prosthetic types, most rotation occurred around the axial y-axis (fig. 5). The axial rotations increased with increasing load. The variations between the specimens were relatively high, but all showed the same trends. All stems, except CEM-3, rotated in the same (negative) direction. From zero to a load of 200N, CEM-3 rotated 0.3 degrees in the positive direction, but for increasing loads again in the same direction as the others. Only one of the four cemented stems (CEM-2) produced axial rotations of real substance

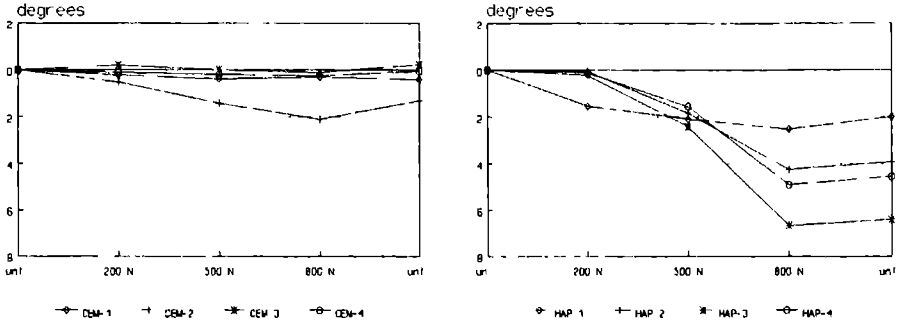

Fig. 5 Axial rotations found for the cemented (left) and the noncemented prostheses (right), from the unloaded case to stepwise increases of load, and again unloaded.

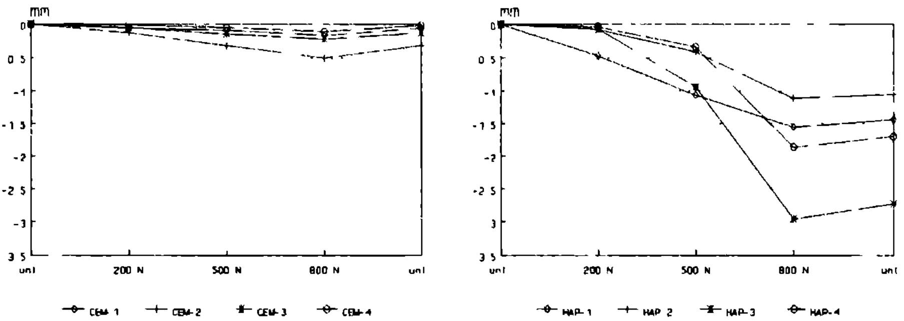

Fig. 6 Subsidence found for the cemented (left) and the noncemented prostheses (right), from the unloaded case to stepwise increases of load, and again unloaded.

(up to 2.1 degrees), those of the other three did not reach beyond 0.4 degrees. The axial rotations of the non-cemented stems were much larger, maximally 2.3 to 6.8 degrees (fig. 5). After subsequent unloading, the major part of these rotations proved to be permanent. Some elastic recovery was evident in both types of specimens, but more pronounced in the cemented stems.

The maximal displacements of the cemented prostheses at the distal tip in mediolateral x- and antero-posterior z- directions were only 0.15 mm. In the noncemented cases, these translations were between 0.07 and 0.77 mm, with one exception (HAP-4, translation in lateral direction of 1.71 mm). In both cases the highest translations occurred in the axial y-direction (fig. 6), resulting in subsidence of the prosthesis relative to bone. These translations followed similar patterns as the axial rotations. They also increased with increasing load. CEM-2 again displayed the highest amount of subsidence of the cemented stems, about 0.5 mm maximally. The subsidence of the other stems was much less. The noncemented stems subsided much more, maximally about 1.1 to 2.9 mm (fig. 6). After unloading there was again some elastic recovery of the subsidence in both the cemented and the noncemented cases, but most of the displacement was permanent. For both translations and rotations under loads of 500 N, 800 N and again unloaded, the results were significantly different in the two types of prosthesis (Student-t test, $p = 0.05$).

Translations were also calculated for the proximal/medial and proximal/-lateral base points of the prosthesis. Interpretation of these results is difficult. These base points are located at some distance (0.5-1.0 cm) from the prosthetic axis. Therefor, the translations, in x- and z-direction in particular, are magnified by prosthetic rotations. Generally, it was found that the displacements in the y-direction were of the same magnitude for all three base points, with one exception (HAP-4), due to its large distal displacement of 1.71 mm in lateral direction.

DISCUSSION

The use of intramedullary femoral bone grafts in revision cases has been described earlier (Wagner 1987, Tyer et al. 1987), although not in the impacted form used here . Nelson et al. (1992) presented 3 cases using femoral allografts in revision of hip replacement with noncemented stems. A preliminary report using a trial femoral component for impaction of cancellous bone grafts in cemented total hip arthroplasty was presented by Simon et al. (1991). Recently, Gie et al. (1993) reported the results of impacted cancellous allografts for revision surgery with bone cement in cases with femoral bone stock loss in 56 hips with promising short-term results. However, there are no histological or mechanical data in the literature about the behaviour of these grafts.

The femur of the goat has a very hard and smooth endosteal surface, similar to the sclerotic bone often seen endosteally during revision surgery. The femur contains trabecular bone only in the proximal part. By using hand reamers only this trabecular bone in the proximal femur was removed, the influence of the reaming technique on the hard cortical bone limited. Although some biological variation in bone shape may be inevitable in experiments like this, the dimensions of the intramedullary canal are clearly controlled by the grafting technique.

The standard deviations measured are within the range described by Karrholm (1989) for RSA accuracy (SD translations 0.01-0.25 mm, SD rotations 0.03-0.60 degrees). By using the RSA method, only tantalum balls have to be placed in the test-specimens, which is a relatively simple procedure, relative to other methods (Schneider et al. 1989, Walker et al. 1987, Burke et al. 1991). RSA produces a complete and very accurate 3-dimensional reconstruction of the relative displacements of the prosthesis. Of course, the evaluation method is tedious and the RSA system must be available.

The force on the femoral head represented the direction and point of application of the maximal force in the sheep, as reported by Bergmann et al. (1984). This load produces axial, torsional, and bending components, which are considered important in testing the stability of stems (Schneider et al. 1989, Burke et al. 1991, Mjøberg et al. 1984). Bergmann et al. found maximal forces of 110 percent of body weight (1984). The average weight of the goats we used was 55.3 kilogram. So the maximal force of 800 N (144 percent of body weight) seems to be sufficient.

This new technique of bone grafting was evaluated with a cemented and a noncemented prosthesis. The components cannot simply be compared. The dimensions of the intramedullary space are defined by the grafting technique. Because the cementation technique requires space, the dimensions of the cemented prosthesis will always differ from the noncemented prosthesis. In addition, the cemented stem had a collar, contrarily to the noncemented stem. However, this collar never rested on the calcar, but fits within the diameter of the femoral canal. In the literature we found no data for the initial stability of stems fixated in combination with bone grafts. However, the results can be compared with literature data concerning the stability of stems fixated primary THA. Schneider et al. (1989) reported that subsidence and axial rotation occur predominantly in both cemented and noncemented prostheses, although definitely less in the cemented ones. We found the same trends. The better initial stability of the cemented stems is probably due to penetration of cement in the graft. In noncemented cases, the graft construction can definitely not provide enough initial stability, resulting in substantial subsidence and axial rotation in all cases. In the cemented cases, only one stem was initially unstable. The displacements for both types of prostheses were predominantly non-elastic, hence permanent, due to slippage and compaction of grafts. The courses of the curves suggest that forces of more than 800 N would have produced additional displacements for the four noncemented and one cemented stems. Hence, it is unlikely that the stems found stable positions yet. The excessive motions of prosthesis HAP-4, seen both proximally and distally (in medio-lateral direction) were the result of an insufficient distal grafting technique. This was evident on X-rays.

CONCLUSIONS

A technique is developed for severe femoral bone stock loss met in revision surgery of failed total hip arthroplasties using impacted trabecular bone grafts. In a loading experiment subsidence and axial rotations are the most important relative displacements. The initial stability is better in the cemented cases than in the noncemented cases, because of cement penetration within the graft. It is possible that secondary stability is obtained after initial subsidence, when the stems found stable seatings.

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CHAPTER 5

Morsellized allografts for fixation of the hip prosthesis femoral component[1]

- A mechanical and histological study in the goat-

B. Willem Schreurs, Pieter Buma, Rik Huiskes, J.L. Mark Slagter and Tom J.J.H.Slooff

ABSTRACT - To simulate femoral intramedullary bone stock loss in revision surgery of failed total hip arthroplasties a method was developed using impacted trabecular bone grafts. In 14 goats a cemented total hip arthroplasty was performed, fixating the stem within a circumferential construction of bone allografts. After 6 or 12 weeks 4 goats were used for mechanical tests and 3 for histology.
The stability of the stems was determined in a loading experiment with roentgenstereo-photogrammatic analysis; the loads were up to 1.44 times the body-weight. One aseptic loosening was seen with gross movements. In the other cases the most important movements were axial rotations (max. 0.24 degrees under 800 N) and axial translation (max. 0.16 mm under 800 N). After unloading there was some elastic recovery. There were no differences between the 6- and the 12-week groups. Histologically revascularisation and remodeling of the grafts were evident. Bone apposition on and bone resorption of the graft resulted in a mixture of graft and new bone. There was more new bone formation in the 12- week group, but the process was not yet completed. The use of impacted trabecular bone grafts in cases of severe intramedullary bone stock loss seems to be a promising revision technique.

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INTRODUCTION

The main problem for revision surgery of failed femoral stems is bone stock loss, mainly seen in the intramedullary and calcar areas. Several methods to deal with this problem have been described (Amstutz et al. 1982, Callaghan et al. 1985, Turner et al. 1987, Rubash and Harris 1988). However, the results of femoral revisions by simply filling the defects with bone cement are not satisfactory. The uses of different types of structural bone grafts have been described (Borja and Mnaymneh 1985, McGann et al. 1986, Head et al. 1987, Oakeshott et al. 1987). However we think that, following experience with revisions on the acetabular side, massive and structural grafts should not be used (Mulroy and Harris 1990). The use of morsellized trabecular bone grafts in femoral revisions has been described earlier (Tyer et al. 1987, Wagner 1987, Allen et al. 1991, Gie et al. 1993). In our department, a bone grafting technique employing impacted morsellized bone chips in combination with cemented cups was used successfully in severe cases of acetabular bone loss (Slooff et al. 1984). With the development of a special set of instruments, this method could also be used on the femoral side. The stability of the stem in such a graft construction is important. In an in vitro study in femora of the goat, the initial stability immediately after insertion was determined (Schreurs et al. 1991 and 1994, see chapter 4). We now performed an in vivo study to obtain information about the mechanical stability of the stems post-operatively as well as histological data about consolidation and incorporation of the allograft.

MATERIALS AND METHODS

All trabecular bone grafts used were harvested in donor goats under sterile conditions. Most grafts were obtained from the sternum. Other donor sites were the distal femur, proximal tibia and humeral head. Bacterial cultures of the grafts were taken. Grafts were freshly frozen and stored at - 80 °C. until implantation, and then thawed at room temperature. The maximal storage time was 6 months. To prevent bias due to different immunological reactions, familiar relationships between donor and host goat was excluded. However, a standardized graft based on pooled bone grafts was not used. A commercially available total hip prosthesis for dogs (Mathys Bettlach,Switzerland,type 2.30.702) was used (Figure 1). The bone cement applied was Sulfix.

14 adult goats (Capra Hircus Sana) were operated on the right hip under general anesthesia, using standard aseptic techniques. A dorsolateral

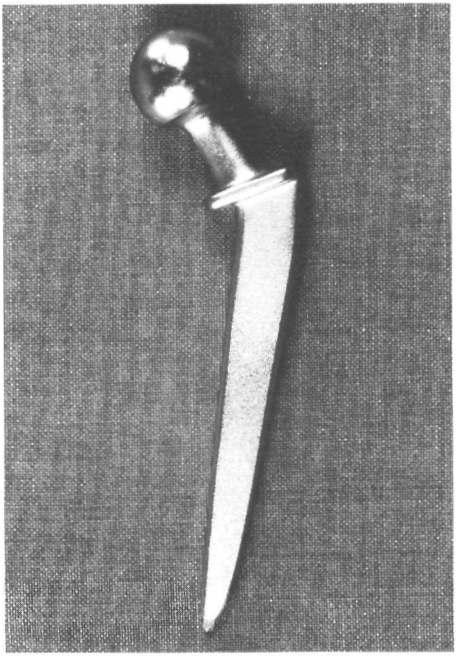


Fig. 1 The femoral prosthesis with a collar.

incision was used and the hip was dislocated. After resection of the femoral head, the acetabulum was prepared and a cemented cup was inserted. The femur of the goat contains trabecular bone only proximally, which was removed using hand reamers (diameter 8-12 mm in 11 cases, diameter 8-14 mm in 3 cases). After cleaning the canal, an appropriately sized bone cement plug (Allo Pro), screwed on a metal rod (diameter 8 mm in 11 goats, 10 mm in 3 goats) was introduced in the medullary canal. The space between this rod and the cortical bone (2-3 mm) was filled with grafts in a retrograde fashion. By means of a special set of instruments, consisting of several types of tubes sliding over the central metal rod, the grafts were impacted (Figure 2). After completion of the filling process, the central rod was unscrewed and removed, leaving a central cavity surrounded by a stable intramedullary wall of bone chips. In this intramedullary bone graft construction a stem was inserted. Cement was injected in a retrograde way in the graft construction, employing a cement syringe (Howmedica). Cement was injected 3.5 to 4 minutes after mixing; the stem was inserted after 4.5 to 5 minutes. For later mechanical testing a tantalum pellet, contained in an acrylic strut, was glued to the tip of the stem prior to insertion. The goats were kept in a hammock for, at most, 2 days after the operation. AP and lateral radiographs were obtained immediately after the operation, after 6 and after 12 weeks. The position of the stem was mostly neutral in the AP and lateral views. In 2 goats, the prosthesis was placed in varus and retroversion, in another there was retroversion only.

Loading patterns of the goats were scored weekly, using visual grading of function as described by Ypma (1981). The goats were kept in cages, allowing free walking, or in the meadow. The goats were killed by an overdose of pentobarbital sodium. In each group, 4 goats were used for the mechanical tests and 3 for histological examinations.

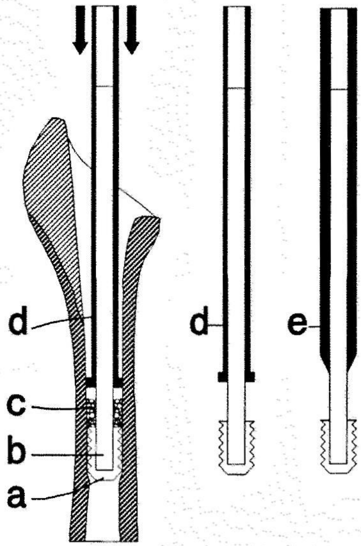


Fig. 2 Schematic representation of the graft impaction technique by using a special set of instruments. A bone cement plug (a) is screwed on a metal rod (b) and introduced into the canal. The space between this metal rod and the cortical bone is filled with trabecular bone grafts (c). These grafts are impacted using metal tubes sliding over the central rod. Different types of tubes are used for axial (d) and radial (e) impaction of the grafts.

Mechanical testing

The 3-D displacements of the prosthesis relative to bone (3 rotations and 3 translations) were measured using Roentgen-Stereophotogrammetic Analysis (RSA) as developed by Selvik (1989). The femora for the mechanical study were freshly harvested and stored at - 80 °C. until testing. After thawing, the femora were resected just above the condyles and the distal part was embedded in polymethylmethacrylate (PMMA). Tantalum pellets were inserted proximal and distal on the medial and lateral sides in the cortical bone. Two small PMMA rods, containing tantalum pellets, were glued to the proximal medial and lateral parts of the prosthesis. Next the prosthesis/bone structures were loaded in an MTS-testing device. Relative to the vertical position, the femora were tilted 15 degrees in a lateral direction, and then internally rotated 45 degrees in order to obtain a

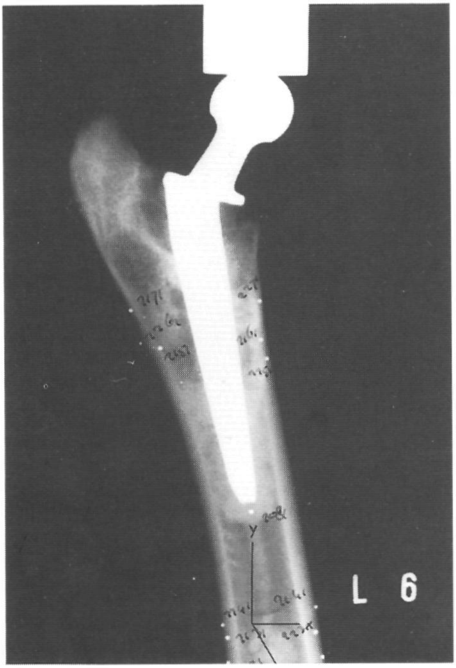


Fig. 3 Femur with bone grafts and a prosthesis. The laboratory coordinate system is shown.

physiological load on the femoral head (Ypma 1981, Bergmann et al. 1984). The load was applied stepwise from zero to 200, 500, 800 N and again unloaded. Each loading period lasted 10 minutes. 5 additional loading cycles were applied to the specimen which had been in situ for 12 weeks.

Stereoroentgenograms were taken before loading, 10 min. after each loading step, and again 10 min. after final unloading. These were evaluated on an Aristomat digitizer, and the 3-D pellet positions were determined with the RSA computer programs. Relative rotations around and translations along the coordinate axes were calculated (Figure 3). To increase the accuracy of the results, all roentgen stereo-films were measured 5 times, and the results averaged.

Histological analysis

The goats received intravital fluorochromes: terramycin (Day 8-12, 25 mg/kg/day), alizaron complexon (6-week group Day 23-27; 12 week-group Day 49-53, 30 mg/kg/day) and calcein-green (6 week-group Day 38-42; 12 week-group Day 80-84, 20 mg/kg/day). The goats were anesthetized and the descending aorta and the vena cava were cannulated. Then they were killed by an overdose of pentobarbital sodium. To visualize the vascularization of the graft, the descending aorta was perfused with at least one liter of a 25 per cent suspension of Micropaque (R) in a physiological saline solution (Rhinelander and Baragry 1962). Thereafter the perfusion was continued with one liter of 12.5 per cent Micropaque in a phosphate-buffered (0.1M, pH 7.4) solution of 4 per cent paraformaldehyde. Both femora were harvested after perfusion by careful exarticulation in the hip and knee joint, leaving an ample musculature cover and intact periost. Further fixation was done by immersion for 1 day in a 3:7 mixture of 4 per cent formalin and 96 per cent ethanol. After removing excess soft tissues, fixation was continued for 10 days in a 4 per cent buffered paraformaldehyde solution.

After fixation, the femora were contact-radiographed and sectioned with a water cooled saw into slices of 2 to 3 mm. Radiographs of the slides were again made. For routine histology the sections were decalcified in 25 per cent EDTA under radiographic control, embedded in PMMA, sectioned (7 μm), and stained with hematoxylin and eosine (HE). For fluorescence microscopy, the slices were dehydrated, embedded in Epon 812, and sectioned (30 μm) on a Leitz rotating diamond saw (Lubbe et al. 1988). The slices for microangiography were decalcified in 5 per cent formic acid under radiographic control, after which the microradiograms were made with a Philips PW 1120 X-ray diffraction spectrophotometer.

All trabecular bone grafts had negative bacterial cultures. The average weight of the goats was 55 kilogram (44 to 66 kilograms). The mean operation time was 4 hours. There were no peri- or post-operative losses of goats. During the operation a small fracture of the proximal femur was seen in 3 cases, once in the calcar zone and twice in the posterior region. There were no post-operative dislocations or clinical signs of deep infections. In one goat (G12-G) a superficial infection of the skin was found at autopsy. All goats loaded the operated leg, although 3 of the 12 goats showed some limp at 6 weeks. After 12 weeks all but 1 goat showed normal walking patterns. 2 goats (G6-D, G6-E) had swollen and painful front legs due to overloading after the operation. These goats were treated successfully with paracetamol for some days.

RESULTS

In one case (G12-D), there was radiographic evidence of subsidence of the prosthesis relative to the cortical bone at 6 weeks and even more so at 12 weeks, with resorption of cortical bone, a radiolucent zone, an extensive reaction of the periosteum and endosteal lysis. In 4 cases (G6-A,G6-E, G6-G and G12-B) a mild proximal periosteal reaction was seen. There were no peri-articular ossifications. In 2 goats (G6-A, G12-D), there was radiographic evidence for cup loosening. On the post-operative radiograms the area in which the graft was located was seen as a homogeneous radioopaque structure. In some after 6 weeks, and in all cases after 12 weeks, this area had become more radiolucent.

Mechanical tests

During mechanical testing, one specimen (G6-D) was lost due to technical problems. The specimen G12-D was considered loose; during the loading experiment excessive axial rotation of 6.1 degrees and subsidence of 3.4 mm were measured. Most rotation occurred around the axial Y-axis in all specimens; the motions around the medial-lateral X-axis and antero-posterior Z-axis were smaller. Although the initial rotation for the 200 N force was not in the same direction in all cases, with increasing load the directions of the rotations showed the same trends (Figure 4). The maximal rotation found was 0.24 degrees (G6-C). After subsequent unloading, there was some elastic recovery in all specimens. The maximal permanent rotation at 10 minutes after unloading was -0.07 degrees for the 6 week-group (G6-B), and -0.14 degrees in the 12 week-group (G12-B).

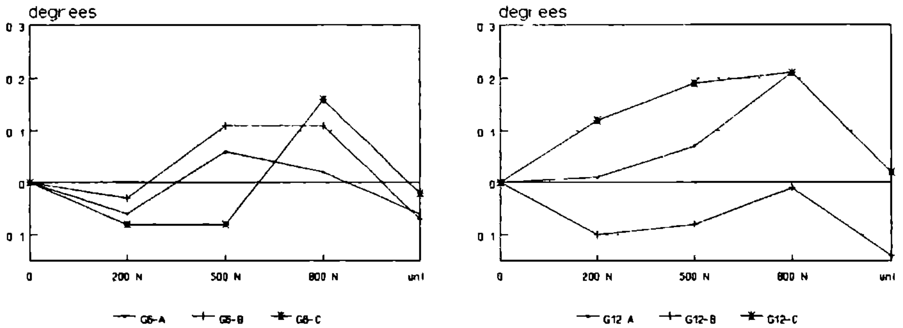


Fig. 4 Axial rotations found for the 6 weeks group (left) and the 12 weeks group (right), from the unloaded case to stepwise increases of load, and again unloaded.

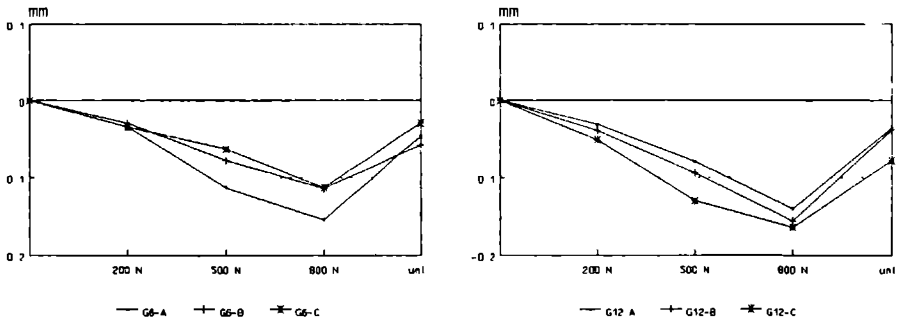


Fig. 5 Axial translations found for the 6 weeks group (left) and the 12 weeks group (right), from the unloaded case to stepwise increases of load, and again unloaded.

In both groups the maximal translations in X- and Z- directions were smaller than in the Y-direction, with 2 exceptions (G6-C; z=0.190 mm, G12-C; x=0.187 mm) (Figure 5). Axial translation increased with increasing load in all cases. After unloading, all specimens showed some elastic recovery. The maximal permanent axial translation after unloading was -0.058 and -0.078 mm for the 6- and 12 week-group, respectively. After 5 additional loading cycles the 12-weeks specimens showed an average additional axial translation of 0.030 mm and an average additional axial rotation of 0.08 degrees. The standard deviations for the displacements measured in the mechanical study were 0.036 mm and 0.07 degrees for translation and rotation, respectively.

Histological study

Contact-radiograms confirmed in detail the change in trabecular appearance of the graft (Figure 6). In two cases (G6-G,G12-F) a fracture line in the cortical wall was seen on the microradiograms. The space between prosthesis and cortical bone was well filled over the entire length, indicating sufficient impaction of the graft. Due to the damage to the endosteal circulation, the inner one-third of the cortical bone had become necrotic. In the cortical wall, a remodeling process of the necrotic bone was seen with resorption and cancellization. The front of remodeling reached the graft after 6 weeks. At locations where no vascular invasion took place the graft consisted of large pieces of trabecular bone showing microfractures due to the impaction process. Histologically, the grafted bone could be easily recognized by the empty osteocyte lacunae or, if seen, the pycnotic appearance of the osteocytes (Figure 7, page 62). Both at 6 and 12 weeks the original medullary fat tissue was replaced by fibrin clot with loose texture.

Ingrowth of the graft by a front of loose connective tissue, small blood vessels and macrophages was seen. The first activity of this revascularization and ossification front was seen after about 25 days in the endosteal cortex. In time, the front penetrated the more central parts of the graft. The process of bone apposition could be followed by the polychrome seqeuntial labeling (Figure 8, page 65). In the process of bone formation, incorporation and lysis of the graft many osteoblastic and osteoclastic cells were seen. This process was not finished after 12 weeks. Graft tissue that was completely embedded in bone cement did not show any incorporation.

After revitalization and incorporation of the graft the architecture of the graft changed, as assessed on the radiograms of the thick sections. The bony structure formed was a mixture of dead bone graft and woven trabecular bone, which was laid down on the graft. Most calcified intra-

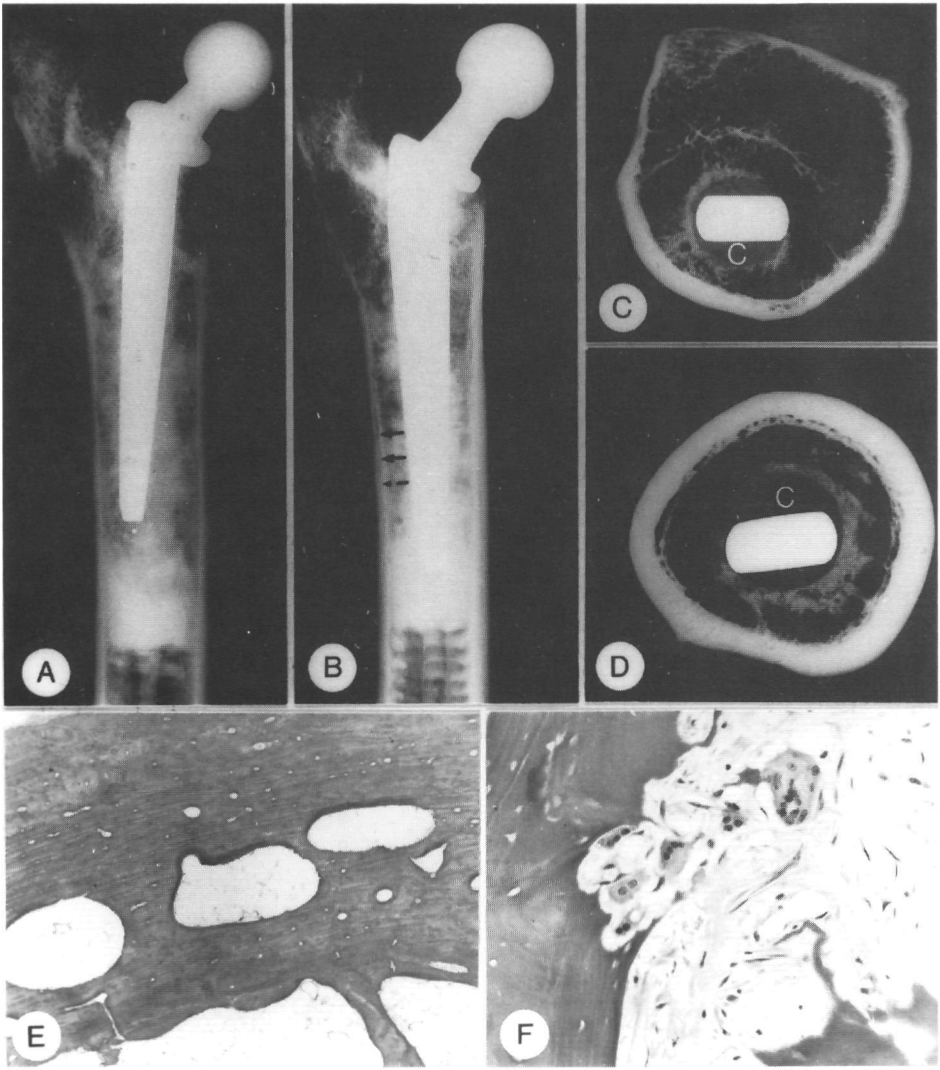


Fig. 6 *A and B Roentgenograms of prostheses after six and twelve weeks, respectively. Note in A the change in trabecular appearance between the lateral proximal and more distal regions around the prosthesis. B Locally a radiolucent reactive line is present in the cortical bone (arrows). C and D Roentgenograms of thick sections of the proximal (C) and mid shaft level (D) of the femur after 12 weeks. Note the orientation of the trabeculae from the cement layer (C) to the preexcisting cortical host bone. E and F Microphotographs. E shows cortical porosis (x30). F Local osteoclastic resorption of the graft. Note empty osteocyte lacunae (x250).*

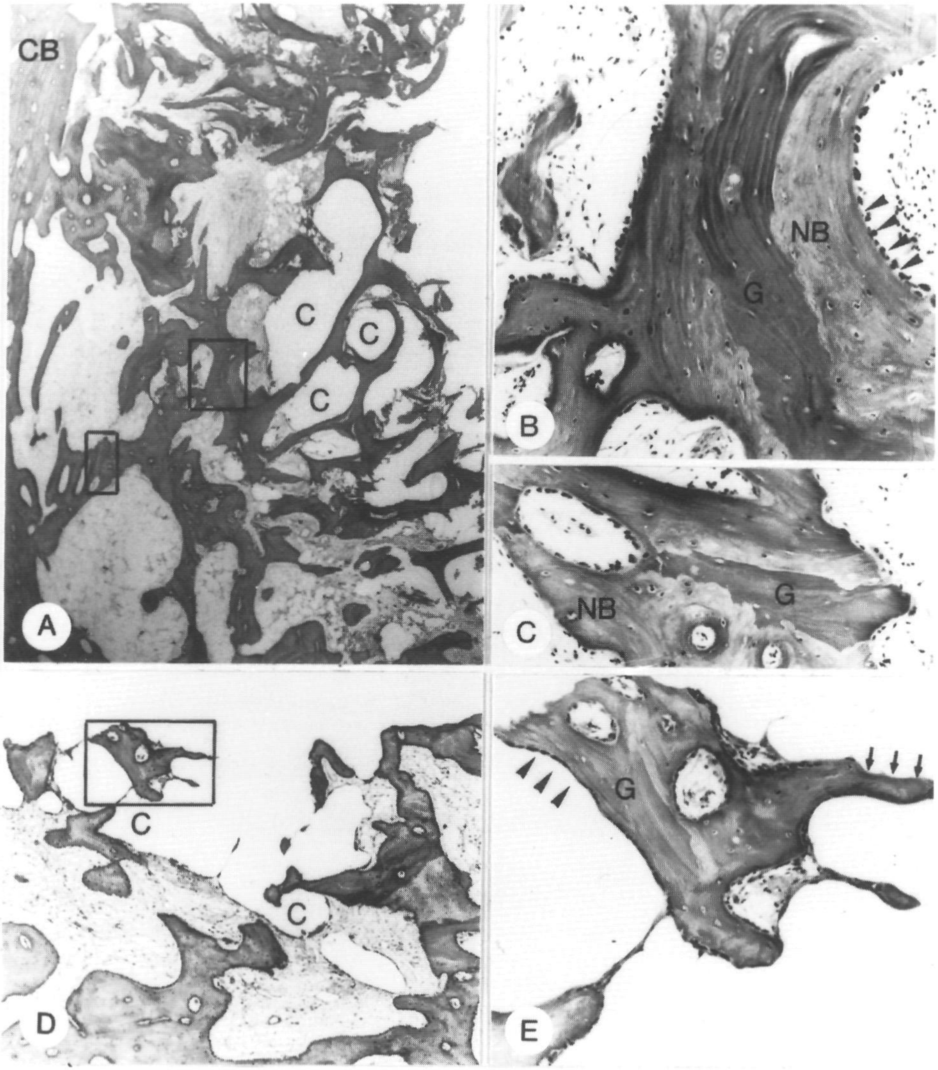


Fig. 7 Microphotographs. Midshaft (A) after 12 weeks. The graft is incorporated into a new bony structure that connects the cement layer (C) with the host cortical bone (CB). Note the penetration of the cement into the graft. x18. B and C Enlargements of the encircled areas in A. Note that the trabeculae are a mixture of new bone (NB) and graft (G). Active osteoblasts are present indicating that active bone remodeling continues. x150. D and E Interface between cement (C) and graft (G). E Enlargement of encircled area in D. The arrows point at a direct contact between cement and bone. Locally a uni-cellular layer is present between cement and bone (arrow heads). D x30, E x110.

medullary bone was located closely around the cement mantle, with bridges of trabecular bone to the cortical wall. This trabecular arrangement was seen in its most complete form at the proximal part of the femur, indicating that the remodeling of the graft proceeded faster proximally than distally.

Cement penetration in the graft was at least 1 mm ; sometimes there was penetration through the graft construction up to the cortical bone. At most places a small soft tissue interface (ca 20-100 micrometer) between cement and graft was seen, with a few multinuclear macrophages found in direct contact with bone cement. Occasionally there was direct contact between new bone and the cement layer.

In the G6-G specimen large numbers of polymorphonuclear leucocytes and lysis of graft and cortical bone were seen, suggestive of infection. There was evidence that an infectious sinus, following the fracture line, was developing. Another specimen (G6-E) also showed signs of infection, although more locally.

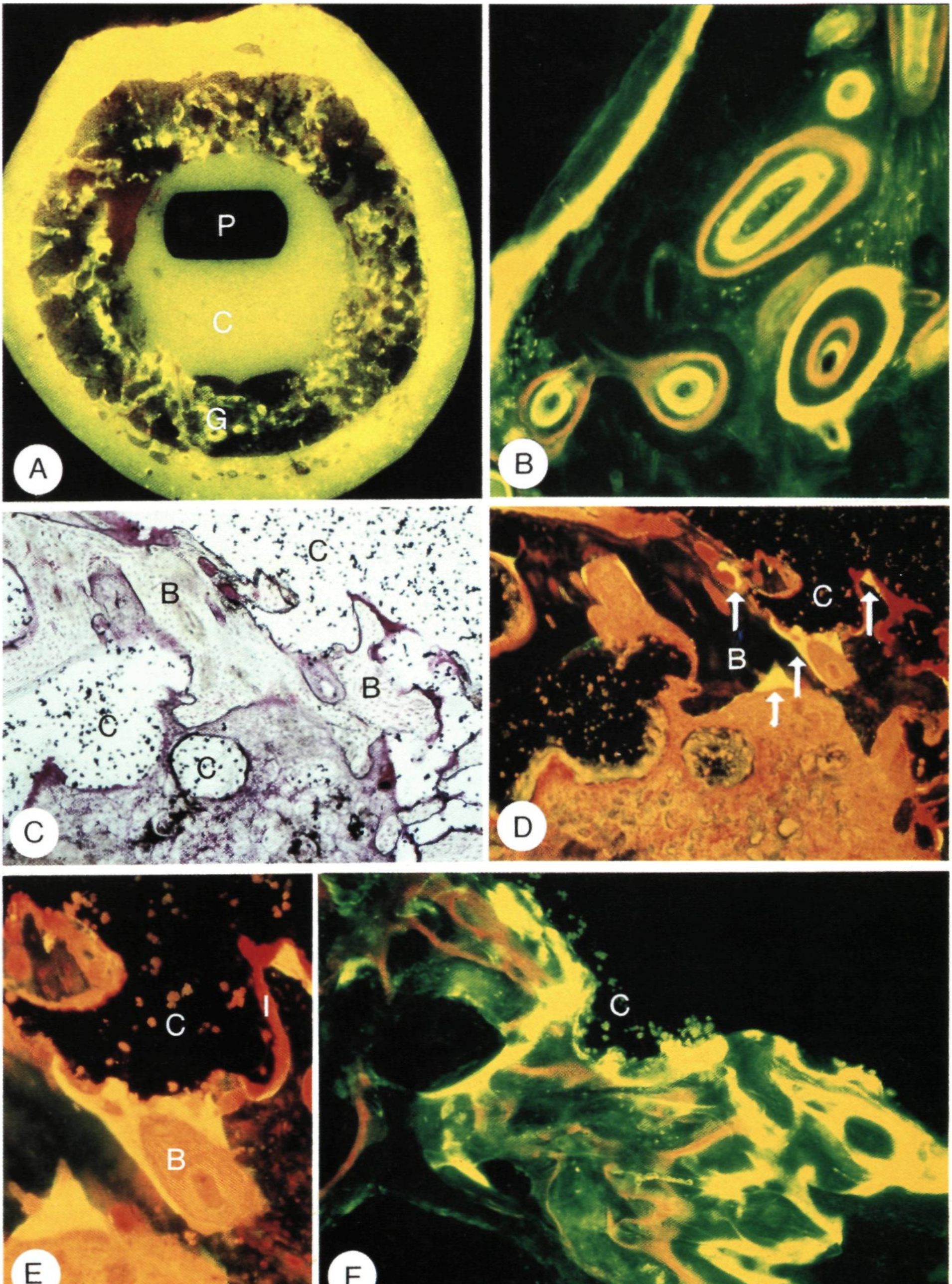
DISCUSSION

The animal model selected for these experiments is thought to be very relevant to the human situation. The femoral canal of the goat is wide enough to perform the grafting technique, and the hard and smooth endosteal surface, with very little trabecular bone, is similar to the sclerotic endosteum usually encountered in revision surgery. The stem shape is similar to the human prosthesis. The goat recovers quickly, and shows normal loading patterns not long after hip surgery, in contrast to dogs. The loads applied in the mechanical testing procedure were realistic at 1.44 times body weight, and even high relative to the loads of 1.10 times body weight measured in vivo by Bergmann et al. (1984) in sheep. The load direction, based on the same measurements by Bergmann et al. (1984) produced axial, torsional and bending components, all essential to assess stem stability (Mjöberg et al. 1984, Schneider et al. 1989, Burke et al. 1991). The RSA technique provides accurate 3-D motions of the stem relative to the bone, and has proved to be easy to use.

The results were certainly not optimal overall, with 1 definite loosening at 12 weeks, and 2 infected cases. Axial translation upon maximal loading was very consistent in the 6- and 12- week specimens at 100-150 micrometers, of which 25 to 50 percent was permanent after the first loading cycle. Another average 30 micrometer of permanent axial translation was added after additional cycles of the 12 weeks group. Although these values were small relative to the precision of the RSA method, they were very consistent, and indicate that the prostheses still sink after 12 weeks when heavily loaded. The rotations were less consistent in values, but the trends pointed in the same direction. On the other hand, these relative displacements, both elastic and permanent, were small when compared to the direct post-operative situation, for which elastic axial translation up to 500 micrometer was measured upon maximal loading, of which 320 micrometer did not recover in one case (Schreurs et al. 1991 and 1994, see chapter 4). Thus the overall implication is that definite improvements in stability occur within 6 weeks provided that failures do not occur, but that the integration process is not fully completed after 12 weeks, as can be derived from the ongoing migration for high loads.

This picture was fully confirmed by the histology. It was shown that the graft revascularizes and incorporates. However, this process had clearly not been completed after 12 weeks, and it seemed to progress faster proximally than distally, probably due to vascular disturbances in the distal cortex (Feith 1975, Rhinelander et al.1979).

Fig. 8 (next page) Fluorescence micrographs. All micrographs are from the same specimen, 12 weeks after the operation. A Low-power fluorescence micrograph of thick section through the distal part of the femur. Note calcein green label throughout the graft (G). P cross-sectioned prosthesis, C cement layer, x 3.5. B Cortical remodeling after insertion of the prosthesis. Orange color is alizaron complexon, the yellow label is calcein gree, x 120. C The cement (C)-bone (B) interface in basic fuchsin-stained undecalcified sawed section at mid-shaft level. D Fluorescence microscopy of the same section showing calcein green label (arrows) in the near vicinity of the cement (C). Note penetration of cement into graft. The orange color is the fluorescence of the basic fuchsin, x 90. E Enlargement of D. Note calcein green labeled bone, and a thin basic fuchsin stained soft tissue interface (I), x 220. F Fluorescence microscopy of unstained sawed section of cement (C) graft interface. The orange color is alizaron complexon, the yellow color is calcein green label of newly formed bone. Note different zones of alizaron complexon and calcein green label, a result of penetration of the front of new bone formation into the graft, x 140.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CHAPTER 6

Biomechanical and histological evaluation of a hydroxyapatite-coated titanium femoral stem fixed with an intramedullary morsellized bone grafting technique.[1]

An animal experiment on goats

B.W. Schreurs, R. Huiskes, P. Buma and T.J.J.H. Slooff

ABSTRACT - To reconstruct femoral intramedullary bone-stock loss in revision surgery of failed total hip arthroplasties, morsellized trabecular bone grafts can be used. In 14 goats a noncemented hydroxyapatite coated titanium stem was fixed within a circumferential construction of bone allografts. After 6 or 12 weeks, 4 goats were used for mechanical tests and 3 for histology. The stability of the stems relative to the bone was determined in a loading experiment with Roentgenstereo-Photogrammatic Analysis (RSA).

Due to 2 loosenings and 2 fractures, only one 6-week specimen and three 12-week specimens were available for mechanical testing. The prostheses were very stable at 12 weeks. The most important movements were axial rotation (maximal 0.17 degrees at 800 N) and subsidence (maximal 0.036 mm at 800 N). After unloading, there was 40-60% elastic recovery. Histological examination showed revascularisation and remodeling of the graft in all the specimens investigated. At the graft site, bone apposition and bone resorption had resulted in a mixture of graft and new bone. Bone incorporation was mainly seen in the proximal areas. Graft lysis was evident in the midshaft region and at distal levels around the prostheses.

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INTRODUCTION

Despite the impressive results of cemented total hip arthroplasty, about ten per cent have to be revised within 10 years (Ahnfelt et al. 1990). Aseptic loosening, which is the major long-term cause for revision, is associated with migration of the implant, the formation of a radio-lucent line on X-rays and by bone stock loss. Although cementless prostheses have yielded good short term results (Callaghan et al. 1988, Gustilo et al. 1989), they can also produce lysis and loosening (Maloney et al. 1990).

The main problem encountered during femoral revision is loss of intramedullary bone stock, which is caused by the loosening process itself and by the removal of the prosthesis and cement. The results of femoral revision after simply filling the defect with bone cement are unsatisfactory, even with modern cementing techniques or in combination with long stems (Amstutz et al. 1982, Callaghan et al. 1985, Rubash et al. 1988, Turner et al. 1987). Several grafting techniques to reconstruct the femur, using different types of bone graft, have been described (Allen et al. 1991, Borja and Mnaymneh 1985, Head et al. 1987, McGann et al. 1986, Oakeshott et al. 1987, Wagner 1987). Based on the poor results of revision with structural grafts at the acetabular site, we advise against using this type of graft (Mulroy and Harris 1990). Some authors have advocated the use of only noncemented techniques in cemented revision cases (Hungerford and Jones 1988), but the results of these noncemented revisions are unsatisfactory, with femoral loosening up to 9.5% after one year (Gustilo and Pasternak 1988, Harris et al. 1988, Hedley et al. 1988).

Since 1979, at our department, severe cases of acetabular bone stock loss were successfully restored with a bone grafting technique using impacted morsellized trabecular bone chips (Slooff et al. 1984). In 1988, a special set of instruments was developed for the femoral application of this procedure. Intramedullary reconstruction of the endosteal wall could be achieved with morsellized bone chips.

In the present study, the feasibility of this technique in combination with an experimental noncemented hydroxyapatite(HA)-coated stem was investigated in an animal experiment. The biomechanical stability of the stem 6 and 12 weeks post-operatively was determined with roentgen-stereo-photogrammatic analysis (RSA) (Selvik 1974). The histological analysis focused on the rate of consolidation, the rate of incorporation of the graft and on the interface area between the prosthesis and the bone.

MATERIALS AND METHODS

Fourteen adult goats (Capra Hircus Sana) underwent surgery on the right hip using general anaesthesia and standard desinfection techniques. The dorso-lateral approach was used and the hip was luxated. After resection of the femoral head, the femoral canal was prepared using hand reamers (9-14 mm). The canal was cleaned and an appropriately sized bone cement plug (AlloPro size 3.5-5) was screwed onto a metal rod (diameter 10 mm) which was then introduced into the medullary canal (see Fig. 1). The space between this rod and the cortical bone was filled with chip-like trabecular grafts in a retrograde fashion.

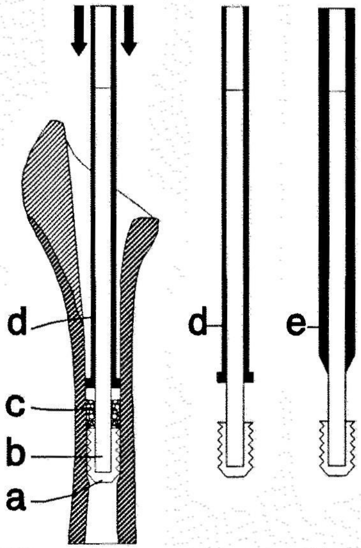


Fig. 1 Schematic drawing of the graft impaction technique using a special set of instruments. A bone cement plug (a) is screwed on to a metal rod (b) and introduced into the canal. The space between the metal rod and the cortical bone is filled with trabecular bone grafts (c). These grafts are impacted using metal tubes which slide over the central rod. Different types of tube are used for axial (d) and radial (e) impaction of the grafts.

Trabecular bone grafts were harvested from donor goats under sterile conditions. Donor sites were the sternum, the distal femur, proximal tibia and humeral head. Per-operative bacterial cultures were taken. All the

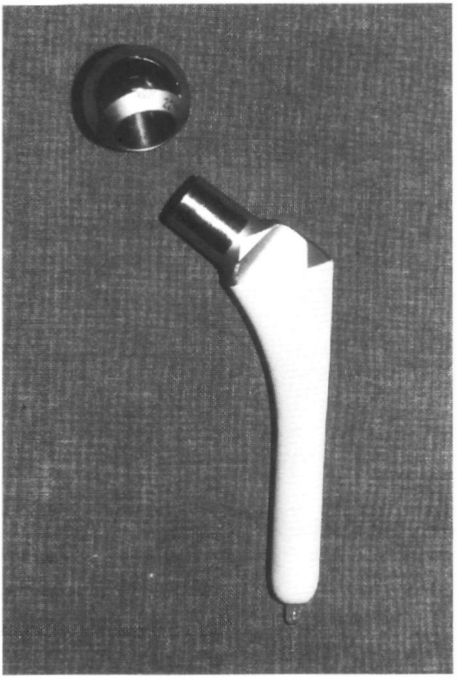


Fig. 2 The titanium prosthesis fully coated with HA.

swabs of the implanted allografts were negative. Grafts were stored at -80° C until implantation. The maximal storage time was 6 months. Before use, the grafts were thawed at room temperature. Using a special set of instruments, consisting of several sizes of tubes sliding over a central metal rod, the grafts could be compressed axially and radially (Fig. 1). After the filling process had been completed, the central metal rod was removed, leaving a central cavity surrounded by impacted graft. A noncemented titanium prosthesis was inserted into this cavity (Ti 6Al-4V ELI Canine Hip Prosthesis by Osteonics, fully coated with HA; thickness 40-60 micrometer; Fig. 2. The HA coating was applied by CAM b.v.; de Groot et al. 1987). An acrylic strut containing a tantalum pellet was glued to the tip of the prosthesis prior to insertion for the RSA measurements. The diameter of the modular femoral head was 22 or 26 mm (CoCr bearing in T 799 alloy). After the operation, the goats were kept in a hammock for 1 - 2 days. Afterwards, they were transferred to cages which allowed free walking. X-rays were taken immediately after the operation, if appropriate at 6 weeks postoperatively and after sacrifice. Loading patterns of the goats were graded weekly using the scoring system of function (Ypma 1981), explained in the results section. Goats were killed after 6 (7 goats) or 12 (7 goats) weeks by an overdose of sodium pentobarbital. In each group 4 goats were used for biomechanical RSA studies and 3 for histological investigation. The motion of the stems relative to the cortical bone were measured with the RSA method described by Selvik [21]. The femora for the biomechanical studies were freshly harvested and stored at -80° C ready for testing. After thawing, the femora were resected just above the condyles and partly embedded in polymethylmethacrylate (PMMA). Tantalum pellets contained in acrylic struts were attached proximally and distally to the medial and lateral sides of the cortical bone, three at each location. Two small acrylic struts containing three pellets each were glued to the medial and lateral aspects of the head of the prosthesis. In this way, two sets of three pellets proximally and one single pellet distally defined the position of the prosthesis. The implanted prostheses were then loaded in an MTS testing machine. Relative to the vertical position, the femora were tilted 15° in the lateral direction and endorotated 45°, in order to obtain a physiological load on the femoral head (Ypma 1981, Bergmann et al. 1984). The load was applied stepwise from zero to 200, 500, and 800 (±10) N (Fig. 3).

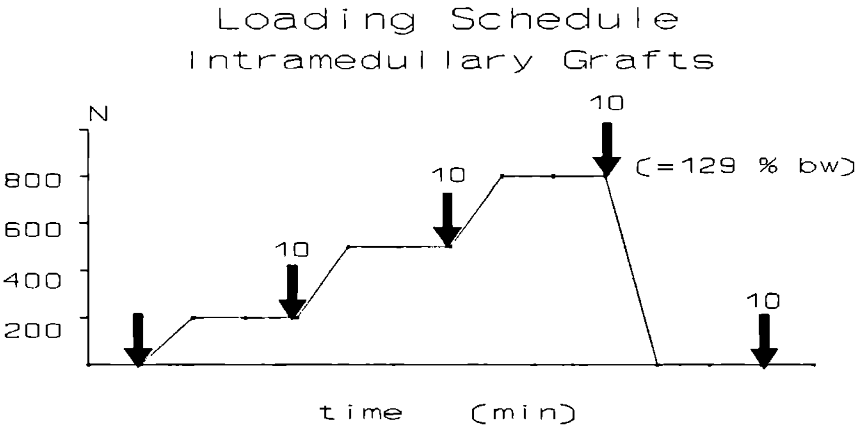


Fig. 3 The loading regime. Roentgenstereograms were taken 10 minutes after increase in load. The arrows indicate when roentgenstereograms were taken.

After each loading step, the load was kept constant for 10 minutes. Before loading, after each loading step and again 10 minutes after the final unloading, stereoroentgenograms were taken. These were measured using an Aristomat digitizer. The 3-D pellet positions at all the time periods during the loading cycle were determined using the RSA computer system. To increase accuracy, all the roentgenograms were measured 5 times and the results were averaged. This method produced translations of the prosthesis relative to the cortical bone along the X axis (lateral-medial translation), Y axis (axial translation, i.e. subsidence), and Z axis (antero-posterior translation). Rotation around the X axis (rotation in the sagittal plane), Y axis (horizontal plane) and Z axis (frontal plane) were calculated. The coordinate system is depicted in Fig. 4.

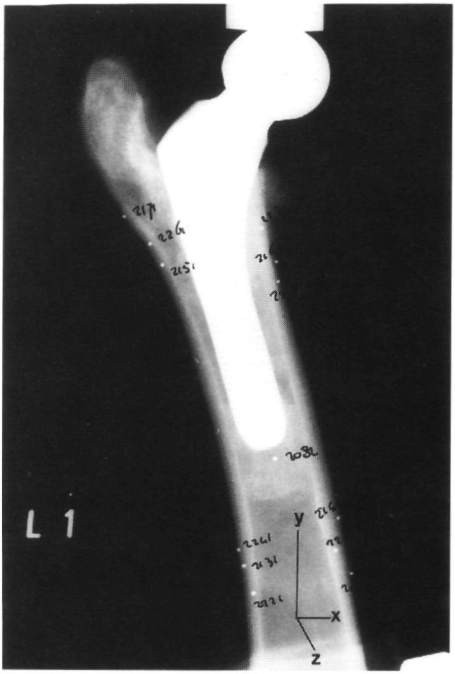


Fig. 4 Femur with bone grafts and a prosthesis. The laboratory coordinate system is shown.

To allow qualitative assessment of bone remodeling, all the goats selected for the histological study received intravital fluorochromes. We used terramycin (days 8-12, 25 mg/kg/day), alizaron complexon (6- week group days 23-27; 12-week group days 49-53, 30 mg/kg/day) and calcein green (6-week group days 38-42;12-week group days 80-84, 20 mg/kg/day) (Frost 1969, Rahn and Perren 1971, 1972). In order to visualize the revascularization of the graft, the legs were perfused with Micropaque(R) according to the micro-angiographic procedure of Rhinelander and Baragry (1962). Both femora were harvested after careful exarticulation and fixed in a mixture of ethanol and formalin. After contact-roentgenograms had been taken, the femora were cut into slices of 3 mm with the prosthesis still in situ. The sectioning scheme allowed observations along the entire length of the prosthesis. To study the bone-prosthesis interface and the integrity of the HA layer, the slices were studied using routine, fluorescence and confocal microscopy. To facilitate further standard histological analysis, the titanium prosthesis core was removed. For micro-angiography, slices were decalcified in formic acid under radiological control. For fluorescence microscopy, 30 μm thick sections were cut on a rotating diamond saw after the slices had been embedded in PMMA (Lubbe et al. 1988). For routine histology, slices were decalcified in EDTA, embedded in PMMA, sectioned and stained with HE.

RESULTS

Clinical observations

The average weight of the goats was 62.2 kilograms (48-77 kg). There were no peri-operative losses. The mean operation time was 3.5 hours (3.1/4-4.1/4 h). Two goats of the 6-week group were lost to follow-up due to a fracture of the operated femur at the tip of the prosthesis. In one case a spontaneous fracture occurred 5 weeks after the operation (G6-C), in the other case the fracture occurred after trauma during transportation from one cage to another (G6-D). The loading patterns of the goats are graphically represented in Fig. 5A and B. All the goats loaded the prosthesis during walking, except for G6-B. At sacrifice, 3 prostheses showed rotational instability (G6-B, G6-E, G12-D).

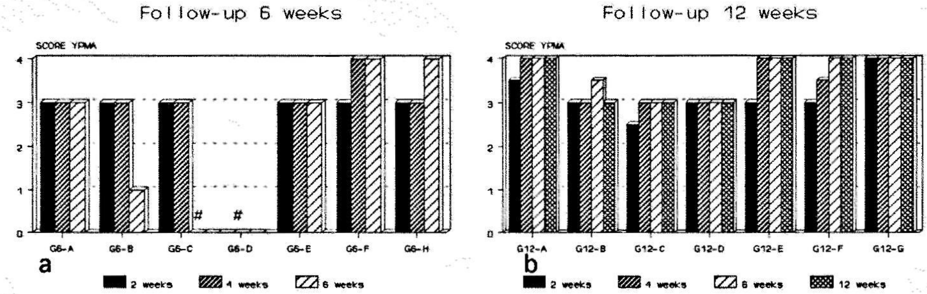


Fig. 5 a/b. Grading of weight bearing post-operatively according to Ypma (1981). Goats were scored weekly; the scores at 2, 4, 6, and 12 weeks are presented.
0 = not used at all
1 = supported incidentally
2 = loaded in standing position and incidentally while walking
3 = loaded in standing position and walking, but with a limp
4 = normal standing and walking

Radiological observations during the clinical phase

Most of the prostheses were placed in a neutral position, although some slightly in varus (Fig. 8C). In one goat (G12-E) a fracture occurred in the calcar zone which was evident during the operation. However, fracture healing was seen. Subsidence was estimated on the AP and lateral standard radiograms. Due to standardization problems of the clinical radiograms, precise measurements were hampered. All but 4 cases showed gross subsidence of several mm of the prosthesis at 6 weeks relative to the immediate post-operative position. No subsidence was observed in any of the goats in the period 6-12 weeks. On the post-operative radiograms the area in which the graft was located was seen as a homogeneous radio-opaque structure. In most of the cases after 6 weeks and in all of the cases after 12 weeks, this area was more radiolucent (Fig. 8B, C).

RSA measurements

The standard deviations for the displacements in the RSA study were estimated to be 0.036 mm and 0.07 degrees for translations and rotations, respectively. Due to the two fractures and one evident loosening, only one

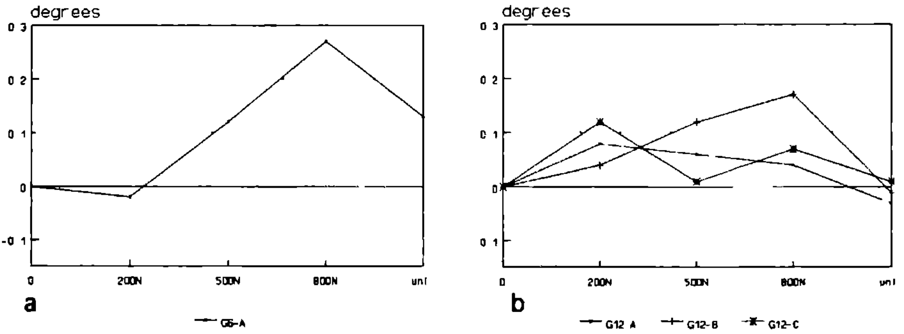


Fig. 6 Axial rotations found for the specimens in the 6-week group (a) and in the 12-week group (b), from unloaded to stepwise increases in load, to again unloaded.

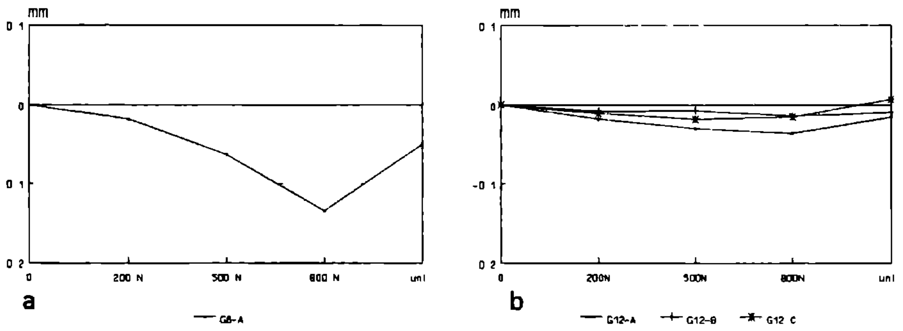


Fig. 7 Subsidence found in the 6-week specimens (a) and in the 12-week group (b), from unloaded to stepwise increases in load, to again unloaded.

specimen was left for biomechanical testing at 6 weeks (Figs 6A, 7A). In the 12-week group, 3 specimens could be used; one was lost due to evident loosening (Figs 6B, 7B). Any translations and rotations were small. Figs 6 and 7 show a graphical representation of the Y translation, resulting in subsidence of the prosthesis relative to the cortical bone and the psi rotation around the Y axis, resulting in axial rotation of the prosthesis. Rotations and translations in the other directions were generally much smaller (except for G12-B; transl. x direction under 800 N was 0.115 mm). In all the cases subsidence increased with load. After unloading, elastic recovery occurred, which resulted in very small permanent translations and rotations. After 5 additional loading cycli, the 12-week specimens showed an average subsidence of 0.009 mm and an average additional rotation of 0.03 degrees.

Histological analysis

The loosening of specimen G6-E was due to a histologically suspected infection. It was discarded from further histological analysis.

The roentgenphotos of the whole bones suggested local differences in the incorporation of the graft into a new trabecular structure (Fig. 8B, C). Radiolucent areas were found particularly at midshaft levels which indicated that complete incorporation had not taken place (Fig. 8B). Therefore, proximal, midshaft and distal levels were studied separately. Changes in the architecture of the graft were confirmed in detail on the contact-roentgenograms of the slices (Fig. 8D/E) and histologically. In three cases microfractures were found in the proximal cortical bone.

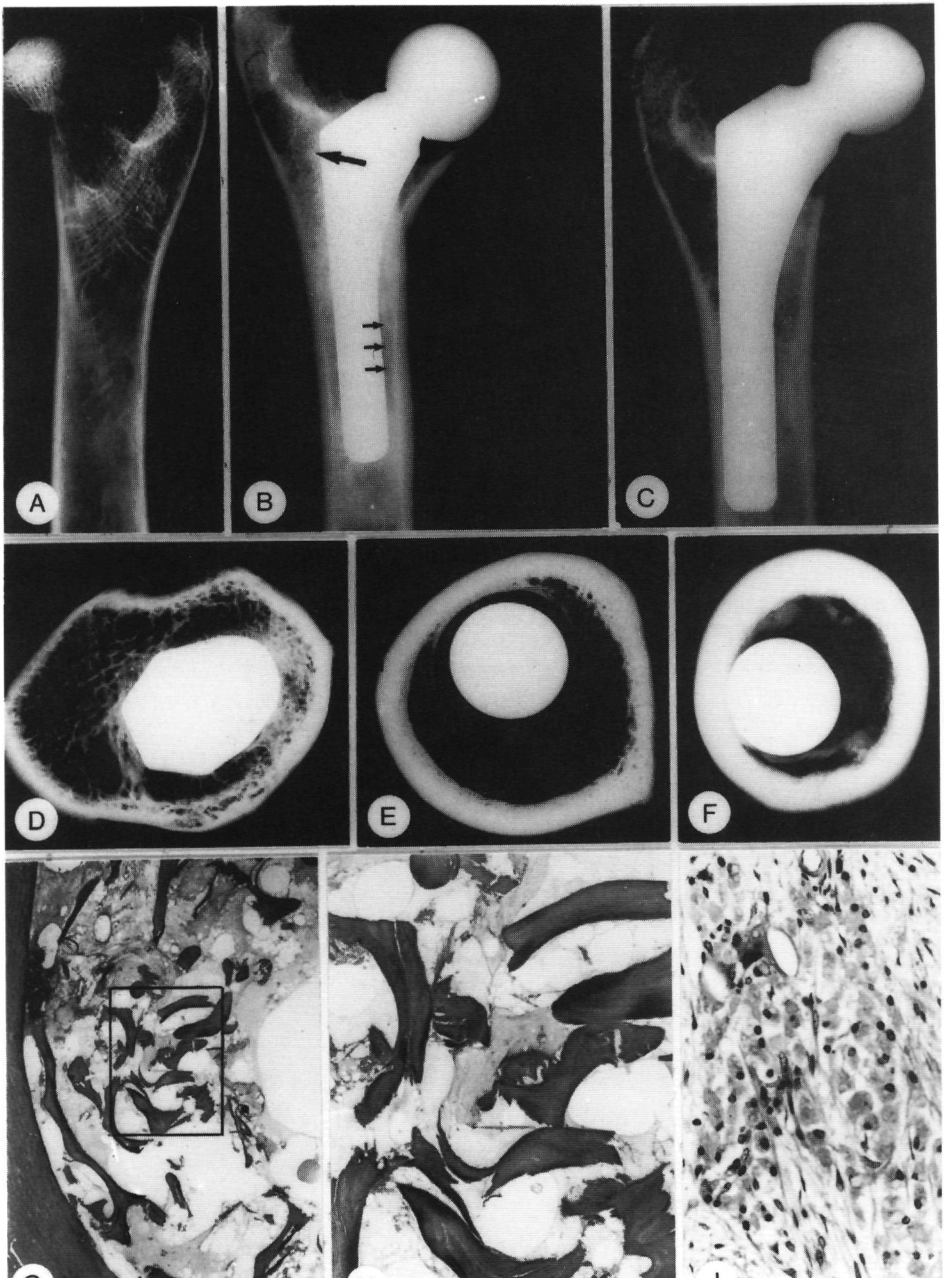
At locations where no vascular invasion had taken place, the original medullary fat tissue had been replaced by a clot with loose structure. The graft itself consisted of large pieces of trabecular bone which showed microfractures due to the impaction process (Fig. 8G, H). Histologically, the grafted bone could be easily recognized by the empty osteocyte lacunae or, if present, the pycnotic appearance of the osteocytes (Fig. 9A, B, D). There was ingrowth in the graft and vascular elements, loose connective tissue, macrophages, osteoblasts and osteoclasts were seen. (Fig. 8J). Distally, we observed that revascularization of the graft took a few weeks longer, due to damage to the compact cortical bone induced by the operation. Many osteoclasts and osteoblasts were involved in the process of bone lysis, formation and incorporation of the graft (Fig. 9B, D, H). The bony structure formed was a mixture of necrotic bone graft and woven trabecular bone, which had been laid down on the graft (Fig. 9B, D).

At proximal levels, revascularisation, incorporation and remodelling of the graft was seen at the lateral trochanteric site after 6 weeks and the trabeculae had formed interconnections with the pre-existing host bone at the corners of the prosthesis (Fig. 9A, B). At 12 weeks revascularisation and incorporation were also seen on the medial side, although less pronounced than on the lateral side. Both fluorescence microscopy and confocal microscopy showed very close contact between the graft and the HA (Fig. 9C). The distance of new bone to the metal ranged between 40 and 60 μm, which indicated that there was direct bone HA contact. This was confirmed by the histological sections after the prosthesis had been removed. A layer of HA was present at the locations where bone-ingrowth had occurred into the HA (Fig. 9E). Although there was fracture healing in G12-E, there was no proximal bone-HA contact. Instead a fibrous layer of 300 μm thick had formed (Fig. 9F), with loose HA crystals at the interface. Trabecular bone had developed in a shell around this fibrous interface. Polarized light showed that the orientation of the collagen fibres was perpendicular to the surface of the prosthesis.

After 12 weeks most of the graft had disappeared at midshaft levels (Figs 8E, 9G, H). The process of osteolysis took slightly longer than 6 weeks to start. Many osteoclastic cells were present and were responsible for resorbing the graft (Fig. 9H), which had been replaced by loosely organized fibrous tissue. From the cortical wall this fibrous tissue was found deposited by woven callous bone, which had never made direct contact with the prosthesis (Fig. 9G).

After 12 weeks some areas of the graft were still present in the original non-revascularized form at distal levels around the prosthesis (Fig. 8G, H). Similar phenomena were also observed at midshaft levels. After revascularization graft lysis predominated (Fig. 8F). Microscopy showed that a bridge of new bone had formed between the tip of the prosthesis and the cortical bone, especially if the prosthesis had been placed with some degree of valgus (Fig. 9J, K).

Fig. 8 A, B, C. (next page) *Roentgenograms of control status (A), and implant status after 6 (B) and 12 weeks (C). Note the proximal trabecular bone in A and the different zones of bone incorporation in B. The roentgenological appearance of the proximal graft has changed from a diffuse appearance to a trabecular structure (large arrow). At midshaft levels (small arrows) the graft is radiolucent. D, E, F, Roentgenograms of thick sections at proximal (D), mid-shaft (E) and distal levels (E) along the prosthesis in the 12-week group. Microphotographs (HE-staining) (G) Graft after impaction but before incorporation. x15. (H) Enlargement of the encircled area in G. x45. (J) Granulation reaction associated with wound healing and graft incorporation after 6 weeks. Note the many histiocytes. x250.*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DISCUSSION

The animal model selected for this experiment is thought to be quite pertinent to the human situation. The femoral canal of the goat is wide enough to perform the grafting technique; the hard and smooth endosteal surface has very little trabecular bone and is similar to the sclerotic endost usually encountered in revision surgery of failed hip prostheses. The goat is fairly adaptable and shows normal loading patterns soon after hip surgery, in contrast to dogs. The stem shape is similar to that of human prostheses. Because of the superior bone inductive capacities (Cook et al. 1988, Geesink et al. 1987, Oonishi et al. 1989, Stephenson et al. 1991), a HA coating was applied which had the same properties as the one used for human prosthesis. HA produces to the enhanced fixation of load-bearing implants (Thomas et al. 1989). Recent studies of loaded and initially unstable implants have confirmed the effect of HA coatings even in the presence of a motion-induced fibrous membrane around the implant (Søballe et al. 1992). HA has a superior gap healing influence to a distance of 2 mm but the influence of HA on the incorporation of unloaded trabecular allografts is not clear (Søballe et al. 1991). No comparable data are available in the literature on a loaded model.

The loads applied in the biomechanical testing procedure were realistic at 129% of body weight and were even high relative to the loads of 110% of body weight measured in vivo in sheep (Bergmann et al. 1984). Based on the same measurements (Bergmann et al. 1984), the load direction produced axial, torsional and bending components which are all essential to asses the stability of the stem (Burke et al., Mjøberg et al. 1984, Schneider et al. 1989). The RSA technique provided accurate 3-D motions of the stem relative to the bone and proved to be easy to use.

Although immunotyping of the goats was considered, it was not applied due to difficulties expected in the interpretation of results with such a relatively small series of animals (Nesse and Larsen 1987, Van Dam et al. 1976). To prevent bias due to immunoresponse, however, the donor goats were obtained from other breeders than the receptor goats, so close consanguineous relationships were excluded (Bos et al. 1983).

Our failure rate was relatively high. Only four of the eight specimens could be used for biomechanical testing and another specimen intended for histological analysis showed loosening due to infection. During impaction of the grafts a fracture appeared peroperatively in one femur because the femur of the goat is very hard and brittle. However, after initial subsidence the prosthesis gained secondary stability. No more fractures were observed in the clinical roentgenstudy, although the microradiograms taken in the histological study frequently showed repaired microfractures of cortical bone. It is possible that these intra-operatively induced microfractures were responsible for one fracture and the two loosenings. The other fracture was caused by trauma.

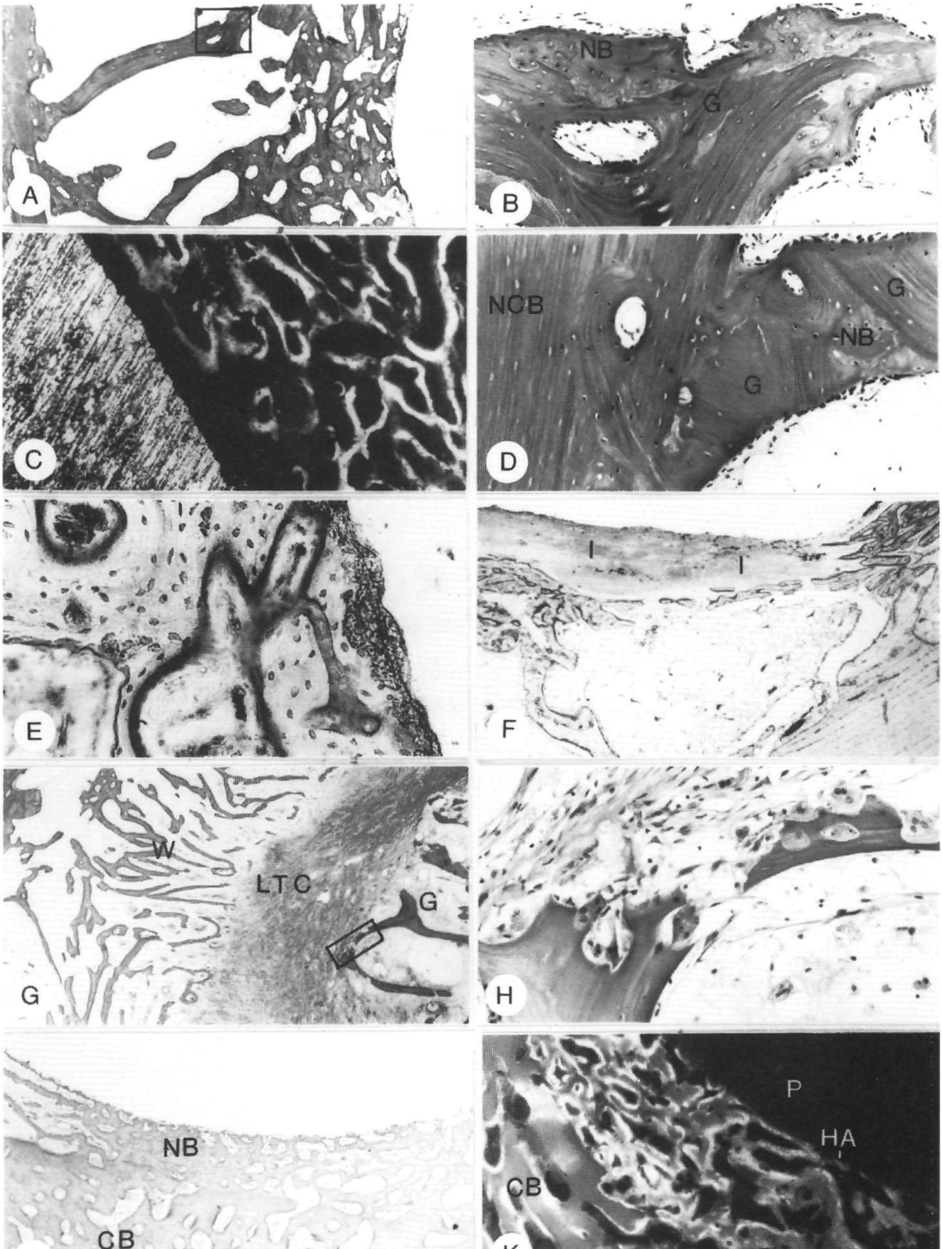
Subsidence upon maximal loading was very consistent in the 12-week specimens at 15-35 μm, of which 40-60 per cent was permanent after the first loading cycle. The 6-week results indicated a trend towards better stability with increasing time. After 5 additional loading cycli, the 12-week specimens showed additional permanent subsidence of 9 μm. Although these values were small relative to the precision of the RSA method, they were very consistent and demonstrated that the prostheses were stable after 12 weeks when heavily loaded. The rotations showed less consistent values, but the trends pointed in the same direction. These elastic and permanent relative displacements were very small when compared to the direct post-operative situation in which elastic subsidence of up to 2955 μm and axial rotations of up to 6.8 degrees were measured upon maximal loading; in one case 2722 micrometer of subsidence did not recover (Schreurs et al. 1994, see chapter 4). We did not find any data in the literature on the stability of noncemented stems fixed within bone grafts. However, to facilitate bone ingrowth in porous coated prostheses, the maximal relative motion allowed between the prosthesis and the bone is 28-40 μ (Burke et al. 1991, Pilliar et al. 1986). Thus secondary stability can be achieved after initial instability and the estimated micromotions were within the scope of those suggested in the literature to permit bone ingrowth, which was confirmed by histology. We found that the graft had become revascularized and incorporated into a new bony structure, which could be followed by fluochrome labeling. The most incorporation was seen in the proximal lateral area where there was sufficient direct bone-HA contact to transfer stress from the prosthesis to the bone. Graft lysis was seen at midshaft and distal levels. Although the repair of the endosteal microcirculation was not complete on the endosteal surfaces at the mid-shaft and distal levels, even at 12 weeks, it cannot explain this lysis. Regarding the histological ingrowth pattern, this prosthesis will probably generate bone and interface stresses like those estimated for a partly proximally coated stem in a FEM (Huiskes, 1990). The stress pattern (with reduction especially at a distal level) can be the explanation for the level-dependent differences in graft incorporation, which suggests that graft incorporation is partly dependent on load. Proximal bridges of trabecular bone to the corners of the prosthesis were also found in a retrieval study (Bauer et al. 1991). There was good contact between the incorporated graft and the HA coating, especially in the proximal region. However, in one case there was fibrous tissue contact between the prosthesis and the bone. Based on retrieval experiments, it was stated that limited bone ingrowth with extensive fibrous tissue seems to be an effective mean of stabilizing primary porous coated femoral stems (Cook et al. 1991).

In contrast to structural bone grafts (Mulroy and Harris 1990), the use of this revision technique of impacted morsellized trabecular intramedullary allografts in combination with cement is becoming quite popular, both acetabular and femoral (Slooff et al. 1984, Gie et al. 1993). Morsellized trabecular bone grafts are frequently used to fill gaps around noncemented stems. The use of intramedullary femoral bone grafts with cementless devices has been described, although never in an impacted form and loaded by a stem (Tyer et al. 1987, Wagner 1987, Nelson et al. 1991).

CONCLUSIONS

A method is suggested to cope with severe femoral bone stock loss met in revision surgery, using impacted trabecular bone grafts in combination with a hydroxyapatite coated titanium stem. In this first experimental animal study, the results indicate that this technique has a high complication rate. However, is has been shown that impacted grafts can sustain the loaded stems and that incorporation of the graft occurs with a biomechanically stable implant. This technique allows gradual graft incorporation and stability, but it needs to be refined and active prevention of infection is necessary.

Fig. 9.(next page) *(A) HE stained section of the proximal lateral bony structure after 12 weeks. Note the connections between the host cortical bone and the prosthesis (removed for histotechnical reasons). x15. (B) Enlargement of the encircled area in A. Note the bone graft (G) with empty osteocyte lacunae and the new bone with viable osteocytes (NB) x100. (C) Fluorescence microscopy of the proximal bone-prosthesis interface taken with a confocal microscope. The HA layer itself is hardly visible. x50. (D) HE stained section showing consolidation of the graft to the necrotic cortical host bone (NCB). Note the remnants of graft (G) and new bone (NB). (E) Sawed section showing bonding of the bone to the layer HA. x140 (F) Section through the proximal part of cortical bone, showing interface formation. x15. (G) HE stained section of the midshaft after six weeks with newly formed woven bone (W), dense connective tissue (LTC) and the graft (G) (H) Enlargement of the encircled area in G showing osteoclastic graft breakdown. x180. (J) Contact site of the tip of the prosthesis with the cortical bone New bone (NB) had formed between the prosthesis and the host cortical bone (CB). x25 (K) Same location but with fluorescence microscopy. Note the intense labeling of the new bone with calcein green between the cortical bone (CB) and the HA coating (HA) of the prosthesis (P) x30*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CHAPTER 7

The use of impacted cancellous allografts for acetabular and femoral revision surgery[1]

B.W. Schreurs, T.J.J.H. Slooff, R. Huiskes and P. Buma

ABSTRACT - The use of impacted cancellous allografts in femoral revision surgery is gaining more popularity. However, in an animal study there were indications that short-term fixation problems could certainly occur. Hence, we reviewed our first 10 patients with severe femoral intramedullary bone stock loss due to aseptic loosening after a total hip prosthesis in which the defect was reconstructed by impacted morsellized allografts. In 9 patients also an acetabular reconstruction was performed with impacted bone grafts. At a mean follow-up of 24 months all patients were marked clinically improved, there were no signs of radiological loosening and there was radiological evidence of incorporation of the grafts. Signs of short-term fixation problems were not seen. However, in two patients which were revised by using a window-technique femoral fractures were observed.
Impacted morsellized bone grafts can be used at the same time both acetabular and femoral.

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INTRODUCTION

A main problem in revision surgery of failed arthroplasties is bone stock loss, induced by the loosening process itself and by procedures to remove prosthesis and cement. On the femoral side, bone stock loss is mainly seen in the calcar area and in the intramedullary region, often leaving a thin sclerotic cortical wall. The clinical results of femoral revisions by simply filling the defects with bone cement are not satisfactory, even if combined with modern cementing techniques or long stems (Turner et al. 1987, Rubash and Harris 1988). The results of re-revisions or third revisions are even less satisfactory (Retpen et al., 1992). The reduction in cement-bone interface shear strength in revision arthroplasties may be an important reason of the high re-revision rates (Dohmae et al. 1988), and is probably associated with poor bone stock (Kershaw et al. 1991).

In 1978 we started with a bone grafting technique in the acetabulum using impacted morsellized bone chips in combination with cemented cups (Slooff et al. 1984, Kinzinger et al. 1991). This technique was based on the experience of Parker and Hastings (1974) and McCollum and Nunley (1978) in acetabular protrusion. Recently, a study was presented on 83 acetabular reconstructions in 77 patients with a mean follow-up of 5.3 years (2-10 years) with favorable clinical results (Schimmel 1992, Slooff et al. 1993).

In the early eighties we decided to try a similar technique for femoral revisions. We started to fill local femoral defects with tightly packed cancellous chips using the consecutive femoral trial components. However, as the femoral load-transfer mechanism involves a considerable shear component (Huiskes, 1991), whereas acetabular load transfer is predominantly in compression (Dalstra and Huiskes, 1992), we decided that animal experiments should be conducted first, to see if the graft reconstruction could withstand the loads (Schreurs et al. 1990, Schreurs et al. 1991, Schreurs et al. 1994a, see chapter 4).

In the meantime, Nelson et al. (1991) presented such a grafting technique for human application in combination with noncemented stems in a case report. The first reports concerning the use of impacted allografts with cemented stems in humans were reported by Simon et al. (1991) and Gie et al. (1993). To standardize this femoral technique, we developed a revision instrument system (X-CHANGE Revision Instruments System) in collaboration with the Exeter group and Howmedica International.

Because the animal experiments have indicated that short-term fixation problems could certainly occur (Schreurs, 1994b, see chapter 5), we have investigated the short-term (24 months) clinical and radiological results of our first series of 10 patients. The animal experiment showed that 12 weeks after implantation stems were still sinking under heavy loads, although the relative displacements were small. Histology confirmed this picture showing incomplete graft revascularization and incorporation after 12 weeks. The meaning of this observation for the human application was analyzed.

PATIENTS AND METHODS

Between march '91 and november '92 10 revisions were performed with reconstruction of the femoral canal using impacted trabecular allografts. In nine cases the acetabulam was reconstructed at the same time with impacted allografts. All but one patient were operated by one surgeon (TJJHS). All patients were reviewed. The mean follow up time was 24 months (14-34 months). Details of these patients are shown in Table 1. Seven were women and 3 men, and the mean age at revision was 64 years (35-76 yrs). The mean weight was 71 kg (58-84 kg) and the mean length 168 centimeters (158-190 cm). Eight patients were operated on the right and two on the left hip. The primary indication for total hip replacement was primary or secondary osteoarthritis in 8 patients and rheumatoid arthritis in the other 2 patients. The revision was the first in 4 patients, the second in 4 and the third in 2.

Surgical technique

The cancellous allograft bone chips were obtained from femoral heads retrieved at primary hip arthroplasties of the local hospital bone bank. The posterolateral approach was used; in two patients a trochanteric osteotomy was required. All femoral and all but two acetabular components were loose at operation; both components were always removed. The acetabulum was prepared carefully, all bone cement and debris was removed and irrigated using pulsatile lavage. In nine patients which had acetabular bone stock defects chip-like trabecular bone grafts were impacted to reconstruct the acetabulum (Slooff et al., 1984). Next, the cup was cemented.

All femoral bone cement and debris was removed using chisels and curettes. The canal was irrigated using pulsatile lavage. Once, a wire mesh was used in the calcar region because of severe bone resorption. Next the femoral reconstruction was performed with the revision system. A threaded intramedullary bone plug was screwed on the guiding rod and introduced into the canal. The space between this wire and the cortical bone was packed with bone grafts in a retrograde fashion. After insertion of bone cement, an Exeter stem was implanted. This technique has been published recently (Gie et al. 1993). During the operation one patient sustained a proximal femoral fissure during cement extraction. Another

Table 1. *Patient information*

case	age	sex	lgth (cm)	wghth (kg)	side	orig. diagn.	nr earlier revisions	implant removed (type)	f.u. aft. revision (months)	Endo-klinik classific.	pre-op HHS	post-op HHS	Complica-tions
1	76	F	162	60	R	OA	1	Lubinus SP2	34	3	56	76	fracture 23 mo.p.o
2	35	F	165	78	R	OA	1	Muller curved stem	29	2-3	59	101	
3	67	M	190	84	R	OA	0	Unknown	27	3	47	96	
4	66	F	162	60	R	RA	1	Muller straight stem	27	2-3	-	-	fracture 4 mo.p o.
5	69	M	178	67	L	OA	2	Muller straight stem	26	2-3	34	97	
6	70	F	158	62	R	OA	2	Wagner long stem	22	4	24	97	
7	65	F	167	79	R	OA	0	Charnley	22	3	36	90	femoral fissure at operation
8	69	M	180	80	L	OA	1	Lubinus SP2	18	4	59	97	
9	71	F	165	58	R	RA	0	Muller curved stem	18	2-3	37	95	
10	52	F	158	73	R	OA	0	Muller curved stem	14	1	58	100	perforation shaft at operation

patient suffered a posterolateral perforation of the femoral shaft. In both cases no special treatment was necessary.

All patients received anticoagulation therapy, systemic antibiotics, antibioticcally impregnated bone cement and indomethacin to prevent heterotopic ossification. The patients were kept in bed for 6 weeks. They were then allowed walking with two crutches for another 6 weeks, followed by gradual return to full weight-bearing.

Clinical evaluation and radiological evaluation

All patients were seen after the operation at 6 wks, 4 months, 1 year and 2 years p.o. Harris Hip Scores (HHS) were estimated pre-operatively and post-operatively by interview and examination.

All pre- and postoperative X-rays were seen and graded, on a consensus basis, by two surgeons and a radiologist. Pre-operative X-rays were graded according to the Endoklinik Classification of femoral bone stock loss (Engelbrecht and Heimert 1987, Figure 1).

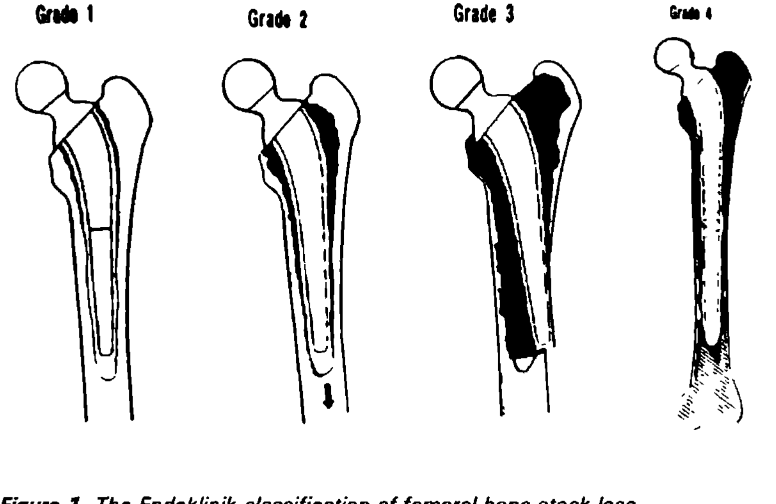


Figure 1. The Endoklinik classification of femoral bone stock loss.
Grade 1. Radiolucent lines confined to the upper half of the cement mantle; clinical signs of loosening.
Grade 2. Generalized radiolucent zones and endosteal erosion of the upper femur leading to widening of the medullary cavity.
Grade 3. Widening of the medullary cavity by expansion of the upper femur
Grade 4. Gross destruction of the upper third of the femur with involvement of the middle third, precluding the insertion of even a long-stemmed prosthesis.

Both the acetabular and the femoral defects were also graded according to the method proposed by the AAOS (D'Antonio et al., 1989, Barger et al., 1993). Acetabular defects were classified as segmental or cavitary. A segmental defect is any complete loss of bone in the supporting hemisphere of the acetabulum. Cavitary defects represent a volumetric loss in bony substance. Femoral bony defects were classified as segmental, cavitary, or combined. Segmental defects represent a complete loss of cortical support in an area. The loss of cancellous bone or endosteal bone with some cortical bone remaining is classified as a cavitary defect. Ectasia refers to loss of endosteal bone with enlargement of periosteal bone surface. Segmental defects were divided into proximal and intercalary defects. Intercalary defects refer to loss of cortical bone with intact bone above and below. The defects were described level-dependent, as well as anterior, posterior, lateral or medial. Level 2 extends 100 mm below the minor trochanter, level 1 is the part of the femur above level 2. Level 3 is below level 2.

After the operation, changes in both the femoral and the acetabular graft reconstruction were studied, focussing on radiological signs of incorporation and remodelling of the graft. Subsidence of the stem within the bone cement was estimated as described by Fowler et al. (1988). Attention was also given to estimate subsidence of the stem-cement mantle relative to the cortical bone.

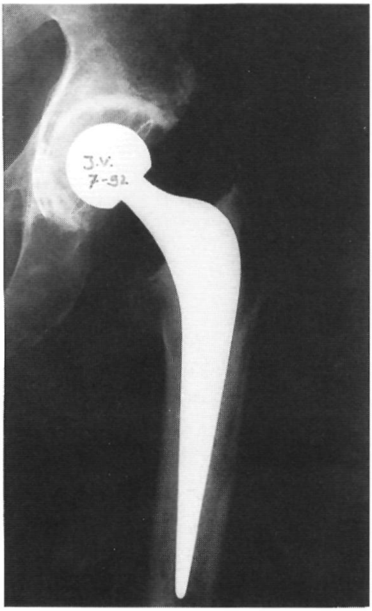
RESULTS

The prosthesis removed was a conventional cemented one in 7 cases. In the three other patients, which had 2 or 3 earlier revisions, long-stemned femoral components were removed, twice cemented and once non-cemented (Table 1). According to the AAOS classification, all acetabular cases showed cavitary defects, both peripheral and central. In 6 of these cases the cavitary defects were combined with segmental defects; 3 showed central defects, in one cases combined with a peripheral defect, and 4 showed only peripheral defects. The pre-operative femoral bone stock loss according to the Endoklinik classification was grade one once, grade two thrice, four times grade three and twice grade four. Femoral deficiencies according to the AAOS showed cavitary defects in all cases, all at levels 1 and 2, and 8 at level 3 as well. In 2 cases segmental defects were observed at level 1; one case showed an intercalary defect at level 2 after a window procedure in a previous revision.

The mean operation time was 4.75 hours (4.25- 6.15 hrs.); the average blood loss was 3300 ml (2150-4700 ml).

The mean pre-operative Harris Hip Score was 46 (24 to 59) (Table 1). The average post-operative grading was 94 (76 to 100). One patient was not

A



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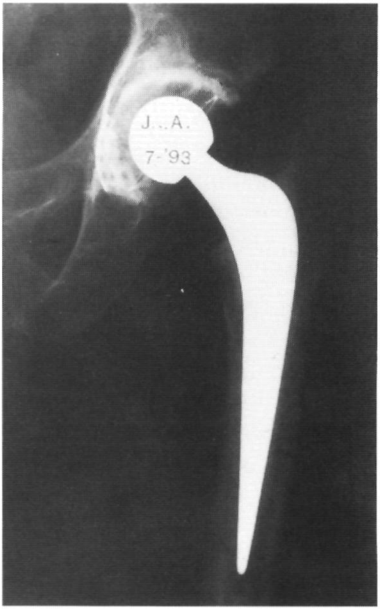

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Figure 2. *X-rays with severe acetabular and femoral osteolysis (a). Situation immediately after revision (b) with both acetabular and femoral reconstruction with impacted morsellized allografts, and situation (c) after 1 year.*

included in the score, because grading was hampered by multiple arthroplasties.

Remodeling of all acetabular and femoral grafts was seen (fig 2a,b,c). The start of this process became visible on X-rays made 4 months after the operation. In most acetabular reconstructions full incorporation of the graft was observed. On the femoral side, trabecular remodeling was also observed. We frequently saw that trabecular remodeling, particularly in the region of the proximal medial cortex, gave the impression of repair of cortical bone. No radiolucent lines were observed around the femoral or acetabular reconstruction. The average subsidence of the femoral stem within the bone cement was 3 mm (0-9 mm). In none of the cases evident subsidence of the cement mantle relative to the cortical bone was seen.

COMPLICATIONS

Two femoral fractures were seen, respectively 3 and 23 months after operation. Both fractures were at the level of the tip of the prosthesis. Both cases had had an earlier revision with a window technique for removing cement and stem. The fracture was treated in one case with a bone plate and once with Partridge plating.

DISCUSSION

Revision surgery will be the challenge for Orthopaedic surgeons in the next decade. Acetabular reconstructions can be performed with impacted morsellized allografts with good clinical and radiographic results (Schimmel et al., 1993). To improve the results of femoral revisions with extensive intramedullary bone stock loss, reconstruction with morsellized grafts was considered (Nelson, 1991, Simon et al., 1991 and Gie et al., 1993). Initially, the grafts were impacted by phantom stems. Based on animal experiments in goats (Schreurs et al., 1990,1991 and 1994a, see chapter 4), a special revision set was developed to facilitate application of the graft. In vitro animal studies confirmed the expectation that the impacted grafts, augmented by cement penetration, were able to provide initial stability for the stems (Schreurs et al. 1990). Later incorporation of the grafts was proven by histology and mechanical testing (Schreurs et al. 1994b, see chapter 5). However, these study also showed that short-term fixation problems could certainly occur because the stems still sink under high loads 12 weeks after implantation.

The technique, however, is technically demanding and time-consuming. Containment of the femur should be complete, or completed by using titanium meshes or other augmentations. Windows should be prevented or, if necessary, strengthened to reduce the risk of femoral fractures. Using the technique carefully, the grafts will be able to resist the load, although some subsidence of the stem was seen also in this study. Using the measuring method reported by Fowler et al.(1988), however, the subsidence of the stem within the cement-mantle can only be estimated by approximation. In no case, evident subsidence of the cement mantle relative to cortical bone was seen. Based on animal experimental results, it seems reasonable to assume any subsidence will take place shortly after implantation.

To estimate remodelling and incorporation of morsellized grafts on X-rays is difficult and not without controversy. However, in animal experiments graft incorporation was proven in both the acetabular (Slooff et al. 1993) and the femoral reconstruction (Schreurs et al. 1994b, see chapter 5).

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CHAPTER 8

Closing remarks

Orthopaedic surgeons should take every opportunity to reduce the failure rate of primary total hip arthroplasty (THA). In a recent study, Schulte et al. (1993) demonstrated long-term survival of hip implants: after a follow-up period of 20 years, 85 percent of all implants were still in situ and functioning well. Unfortunately, most studies show less favorable results, and, given the present state of the art, a eventual revision of a hip implant can be expected. Perhaps, total hip replacement should be seen from the start as a multi-stage treatment (Huiskes, 1993).

Failure rates of THA can be reduced by following some ground rules. Failure rates are influenced by patient-related, surgeon-related and implant-related factors. Careful patient selection, patient education and careful post-operative instructions are still essential. In young patients an arthrodesis of the hip should be considered as a serious alternative to THA, given that this operation combines favourable long term results (FU 15 years) with a high degree of patient satisfaction (Sofue et al. 1989). The skills and experience of the surgeon will influence the failure rates of THA, but failures due to infection are also related to operating room facilities. Clean-air systems are very effective in reducing these infections. A careful implant selection is also very important. A Swedish multi-center trial clearly showed different survival rates for different types of implant (Ahnfelt et al. 1990).

Most THA will fail due to aseptic loosening, a slow but progressive process that often leads to bone stock loss. To prevent excessive bone stock loss, all patients with a THA should be seen periodically for both clinical and radiological investigations (Slooff, 1993). In some cases it might be necessary to perform a revision operation in patients without complaints to prevent devastating bone loss.

Besides causing upheaval to the life of the patient, revision surgery is very expensive. Carter et al (1992) calculated the costs for the average patient having a hip revision at 20.000 UK pounds, excluding the additional costs of the prostheses and drugs used. Revision surgery for loosening due to infection generates even higher costs (Sculco, 1993). Given the present limitations on health expenditure and the very expensive treatment needed for patients with infected total hip implants, the Orthopaedic Department

of the University of Nijmegen -despite its considerable expertise in this field- can no longer accept patients with infected hip implants which were implanted at other hospitals. This problem is expected to become an international as well as a national one, if it is not so already (Sculco, 1992).
At the moment, revision surgery for cases of aseptic loosening, where the primary operation was in another hospital, is still permitted. However, in the case of great financial difficulties, restraints on this kind of surgery can be expected. Revision surgery of failed THAs can be technically demanding, as witnessed in the literature and by the information decribed in this thesis. Referral to a specialized clinic for hip surgery may be necessary. The question then arises of who should pay for the revision of a failed THA. Carter (1992) suggested to include a reservation for future revision surgery in the costs of a primary hip prosthesis. Perhaps another suggestion is to reclaim a part of the costs for revision surgery from the budget of the primary surgeon, thus forcing surgeons to more carefully select patients, implants and operation methods.

Failure rates - especially of the femoral reconstruction - can be reduced by using improved cementing techniques. Cementing techniques can be classified as first, second and third generation techniques (Harris,1994). Initially, cement was inserted by a finger-packing technique without pressurization. Second generation femoral cementing techniques involved the use of an intramedullary plug and the use of a cement gun. Several studies demonstrated the effects of these techniques on aseptic-loosening failure rate (Harris, 1994). Unfortunately, many orthopaedic surgeons still do not use a cement plug or pressurization (Slooff, pers. comm.). Although Schulte et al. (1993) showed recently that excellent results are possible with first generation techniques, some qualifying remarks need to be made. Not only is the hip prosthesis used in this study (Charnley) one of the most successful implants (Ahnfelt et al., 1990), the femoral stem was also inserted in a wide cement mantle. This is more typical for third generation techniques, where one of the goals is to create a broad cement mantle by using centralization of the stem. Other goals of third generation techniques include inter alia pressurization and porosity reduction. It has been suggested that porosity reduction of bone cement will create a cement with a higher fatigue strength. In Chapter 2, four cement preparation techniques are described, with vacuum mixing showing the greatest porosity reduction. The ideal way to address the issue of whether porosity reduction will influence the results of total hip arthroplasty would be a long-term, prospective randomized study. However, it will be difficult to conduct such a study, given the length of time needed and the number of patients. If, as suggested, cement fractures will play an important role in long-term failure mechanisms, vacuum mixing will be beneficial (Wixon 1992).

The number of techniques described in the literature for removing prosthesis and bone cement (Chapter 1) suggests that there is no one optimal technique. In Chapter 3, attention is focused on the feasibility of using the lithotryptor to facilitate cement removal in revision surgery. Because of the limited data on this issue in the literature, the effect of high-energy shock waves generated by the lithotryptor on bone cement was studied. The shock waves were found to cause microscopic lesions in a small area on the surface of cement discs, but these lesions were small relative to the pores usually present in bone cement. However,the effect of the lithotryptor on cement discs which contained these pores was greater then on discs who were free of pores, indicating that these pores probably act as stress risers. At the moment, the technique seems to be of little clinical value because of the technical limitations of the small shock wave focus, which would make the pre-treatment very time-consuming.

Although there was considerable pre-existing experience of reconstructing acetabulae with impacted morsellized bone chips, we decided to perform animal studies, after the development of the revision set for femoral graft impaction. The femoral load-transfer mechanism involves a considerable shear component, whereas the acetabular load transfer is predominantly in compression (Chapter 7). The goal of these animal studies was to see if the stability of the prosthesis and surrounding grafts was sufficient to permit incorporation of the graft (Chapter 4, 5 and 6). Although the animal model we used was not a real revision model, the femoral canal of the goat contains very little trabecular bone and has a hard and smooth endosteal surface, which is quite similar to the sclerotic endosteum usually encountered in revision surgery. These studies showed that it is possible to use impacted morsellized grafts for femoral reconstruction with both cemented and noncemented stems, although the failure rate is high and technical improvements are certainly necessary. Although the trends were clear, the follow up was relatively short, and studies with longer follow-up are therefore still needed. In retrospect, it would have been possible to use the same test-specimen for both the mechanical and the histological study, because the mechanical tests were non-destructive. In future tests, perioperative antibiotics should be used to prevent failures due to infection.

The grafting technique developed has gained some clear advantages by creating a situation which is as close to nature as possible: the intramedullary bone stock loss is restored with grafted bone, and thus bone is replaced by bone. In addition, this grafting technique is combined with a regular THA (Exeter), with favourable long-term follow-up results (Ahnfelt et al. 1990). The first clinical results of the revision technique are promising (Gie et al. 1993, Chapter 7), although the follow-up period is limited. It remains unclear whether these results can simply be assumed to apply for other types of prostheses: the Exeter stem is tapered and has a polished surface and is supposed to subside within the cement mantle (Fowler et al. 1988).

However, some critical remarks should be made. This revision technique is time-consuming and technically demanding. Besides, the availability of bone allografts is a potential limiting factor for this technique even without the expense of bone banking and processing. Perhaps bone substitutes like hydroxyapatite, tricalciumphosphate or bovine denaturated bone can be future alternatives.

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CHAPTER 9

Summary

Despite the impressive results of cemented total hip arthroplasty, about 10 per cent will fail within 10 years post-operatively. Although a failed total hip arthroplasty can be removed in most cases and replaced by another one during a revision operation, these present a number of problems (Chapter 1). This dissertation concentrates on some aspects of revision surgery, especially on the problems met on the femoral side. It is assumed that the fatigue strength of bone cement is an important factor for fixation endurance of both primary and revision prostheses. To improve the strength, reduction of the porosity of the bone cement is critical. Several methods were suggested to reduce porosity. In Chapter 2, an investigation of four acrylic cement preparation techniques is discussed, hand-mixing, pressurization in a pneumatic pistol, centrifugation, and vacuum mixing. The best results were obtained with vacuum mixing, using a newly designed experimental system, yielding porosity reductions of 60-80 per cent relative to hand mixing. Vacuum mixing with a commercial system was also effective, but to a somewhat lesser extent.
Two main problems are met in revision surgery of failed cemented total hip arthroplasties: How to remove the prosthesis and the bone cement and how to cope with severe bone stock loss. The latter is caused by the loosening process itself and by additional damage to the bone during the removal of prosthesis and cement.
To facilitate the removal of cement and prosthesis the applicability of the lithotryptor was studied. In Chapter 3 an investigation is discussed with high-energy shock waves (HESW), generated by the lithotryptor, focussed on discs of polymethylmethacrylate bone cement. The high energy shock waves caused only microscopic lesions on the frontal surface of the discs. The individual lesions were smaller than 0.1 mm, and displayed characteristic shapes. The maximal area porosity caused by HESW was 4 %. The size of the lesions made by HESW were small compared to the pores occuring normally in bone cement. However, microfractures in the cement were only seen in relation with a pore in the focal area, indicating that these pores probably act as stress risers. Although the effect of HESW on bone cement in this in vitro study is limited, in the clinical situation bone cement will be mixed with blood and rests of fat tissue. Moreover, the interface between bone cement and cancellous bone is structurally complex. The effect of HESW on this interface needs further investigation.

In our department, the use of impacted morsellized bone allografts was developed in combination with cemented cups in severe cases of acetabular bone stock loss in revision surgery. The results in the clinical setting were favorable, which led to their application for femoral stem fixation as well. First a special set of instruments was developed for the femoral application of this procedure. Using this set of instruments, femoral intramedullary bone stock loss can be reconstructed with a wall of impacted morsellized grafts. The stability of the stem in such a graft construction is important. In Chapter 4 an in vitro model with femora of the goat was used to study the initial stabilities of both cemented and non-cemented stems in a loading experiment. Displacements of the stems relative to bone were determined with roentgen-stereophotogrammatic analysis. The most important movements were axial rotations (cemented stems up to 2.1 degrees, noncemented stems up to 6.8 degrees) and subsidence (cemented stems up to 0.5 mm, noncemented stems up to 2.9 mm). The initial stability of the cemented stems was better, probably due to cement penetration in the graft layer. In Chapter 5 an in vivo animal study in goats is described, performed to obtain information about the mechanical stability of the cemented stems post-operatively, as well as histological data about consolidation and incorporation of the allograft. The goats were followed for 6 or 12 weeks. Subsidence on maximal loading was very consistent in the 6- and 12-weeks specimens at 0.10-0.15 mm. Although these displacements were small when compared to the direct post-operative situation (Chapter 4), the ongoing migration of stems under repeated high loads indicated that the incorporation process was not fully completed after 12 weeks. The rotations were less consistent in values, but the trends pointed in the same direction. Histologically, revasculari-zation and remodeling was evident. Bone apposition and bone resorption of the grafts resulted in a mixture of graft and new bone. There was more new bone formation in the 12-week group, but the process was not yet completed. Hence, the stability of loaded cemented stems in combination with impacted morsellized allografts permitted incorporation of the graft.
In Chapter 6, a study is described with the same in vivo goat model, performed to obtain information about the mechanical stability of the noncemented titanium stems post-operatively, as well as histological data about consolidation and incorporation of the allograft. The post-operative failure rate was relatively high. Only four of the eight specimens could be used for mechanical testing, thus only one 6-week specimen and three 12-weeks specimen were available for mechanical testing. However, these stems were very stable for both subsidence (maximal 0.036 mm) and axial rotation (maximal 0.17 degrees) and even under repeated high loads. These stems achieved a secondary stability which was dramatically improved relative to the estimated initial stability (Chapter 4). Histological examina-

tion showed revascularization and remodeling of the graft in all specimens investigated. Bone apposition and bone resorption had resulted in a mixture of graft and new bone. Bone incorporation was mainly seen in the proximal areas. Graft lysis was evident in the midshaft region and at distal levels around the prosthesis. It was shown that the impacted grafts can sustain the loaded noncemented stems and that incorporation of the grafts occurred with the biomechanically stable implant. However, the failure rate was high, probably as a result of lacking in initial stability. The technique needs to be refined.

Based on the animal revision set, a human revision set (X-CHANGE Revision Instruments) was developed in collaboration with the Princess Elizabeth Orthopaedic Hospital, Exeter, U.K. and Howmedica International. In Chapter 7 our first clinical experience is reported, as done in 10 patients with a mean follow-up of 24 months. The application of impacted morsellized allografts in cases with severe femoral intramedullary bone stock loss seems a promising reconstructive option. However, only long-term studies can establish estimate the true value of this technique.

Samenvatting

Ondanks de indrukwekkende resultaten welke worden behaald met gecementeerde totale heuparthroplastieken wordt aangenomen dat 10 procent van de geimplanteerde heupen binnen 10 jaar na de operatie faalt. In de meeste gevallen kan de gefaalde heuparthroplastiek na verwijdering worden vervangen door een andere prothese. Deze revisie-operaties gaan echter gepaard met de nodige problemen (Hoofdstuk 1). In dit proefschrift zijn enige aspecten van de revisie-chirurgie van heupprothesen bestudeerd, waarbij de aandacht vooral werd gericht op de problematiek aan femorale zijde.
Er wordt verondersteld dat de vermoeiingssterkte van botcement een belangrijke rol speelt in de uiteindelijke overlevingsduur van zowel een primaire als een gereviseerde gecementeerde prothese. Door middel van een reductie van de porositeit van het botcement is deze vermoeiingssterkte waarschijnlijk te verbeteren. Verschillende methoden van botcementverwerking worden gepropageerd ter reductie van de cement-porositeit. In Hoofdstuk 2 zijn vier methoden van cementverwerking onderzocht: manueel mengen, voorcomprimeren van aangemaakt cement in een pneumatisch pistool, centrifugeren van cement en mengen van cement onder vacuüm. De beste resultaten werden verkregen bij mengen onder vacuüm in een zelf ontwikkeld experimenteel systeem, waarbij een vermindering van de porositeit werd verkregen van 60-80 procent ten opzichte manuele menging. Vacuüm mengen met een commercieel verkrijgbaar systeem was ook effectief, zij het in iets mindere mate.
Twee hoofdproblemen binnen de revisie-chirurgie van gefaalde gecementeerde heuparthroplastieken zijn: a) hoe de prothese en het botcement te verwijderen en b) wat te doen met het vaak aanwezige ernstige botverlies. Dit botverlies wordt veroorzaakt door het loslatingsproces zelf alsmede door extra botbeschadigingen welke optreden tijdens het verwijderen van prothese en cement.
In Hoofdstuk 3 werd de mogelijke toepassing van de niersteenvergruizer onderzocht om het verwijderen van prothese en cement te vereenvoudigen. Daartoe werden de door de niersteenvergruizer opgewekte hoog energetische drukgolven gericht op schijfjes polymethylmethacrylaat botcement. Deze golven veroorzaakten slechts microscopische beschadigingen op de voorzijde van deze schijfjes. De individuele beschadigingen waren kleiner dan 0.1 mm en hadden een typische vorm. De maximale oppervlakteporositeit veroorzaakt door de drukgolven bedroeg 4 %. De beschadigingen werden ook bestudeerd met behulp van scanning elektronen microscopie. De afmetingen van deze beschadigingen waren klein ten opzichte van de poriën welke normaal in botcement worden aangetroffen. Soms werden microfracturen in het cement gezien welke dan meestal uitgingen van een

porie. Blijkbaar zijn deze poriën gebieden met verminderde weerstand tegen drukgolven. Geconcludeerd werd dat het effect van de niersteenvergruizer op schijfjes botcement in deze in vitro studie beperkt was. In de klinische situatie zal botcement echter gemengd zijn met bloed en resten vettig beenmerg; bovendien is de interface tussen botcement en het trabeculaire bot een zeer complexe structuur. Het effect van de niersteenvergruizer op deze interface dient nader onderzocht te worden.
Voor revisies waarbij sprake is van ernstig acetubulair botverlies is door het Instituut voor Orthopedie van het AZN een methode ontwikkeld, waarbij dit acetabulum gereconstrueerd wordt met geimpacteerde bottransplantaat-fragmenten (botchips). Vervolgens wordt een gecementeerde acetabulaire cup geplaatst. Gezien de goede klinische resultaten met deze techniek is onderzoek verricht naar de toepasbaarheid van deze methode aan de femorale zijde. Allereerst werd een experimenteel instrumentarium ontwikkeld voor de femorale toepassing van deze techniek. Met behulp hiervan was het mogelijk een concentrische wand van geimpacteerde botfragmenten binnen een femur op te bouwen.
De stabiliteit van een femorale prothese binnen een dergelijke reconstructie van transplantaten is belangrijk. In Hoofdstuk 4 werd, in een in vitro studie met geitenfemora, de stabiliteit van de prothese onmiddelijk na plaatsing onderzocht in een belastingsexperiment. Er werd zowel een gecementeerde prothese getest alsook een ongecementeerde prothese. Deze ongecementeerde prothese was vervaardigd uit titanium en voorzien van een hydroxyapatiet coating. De verplaatsingen van de prothesen ten opzichte van het omgevende corticale bot werden gemeten met behulp van röntgen-stereofotogrammetrie. De belangrijkste bewegingen waren axiale rotatie (gecementeerde prothese tot 2.1 graden, ongecementeerde prothese tot 6.8 graden) en subsidence ofwel axiale translatie (gecementeerde prothese tot 0.5 mm, ongecementeerde prothese tot 2.9 mm). De initiële stabiliteit van de gecementeerde prothesen was beter, waarschijnlijk door de penetratie van cement in het bottransplantaat.
In Hoofdstuk 5 is een in vivo dierstudie met geiten beschreven. Deze studie werd uitgevoerd met gecementeerde prothesen waarbij het doel was informatie te verkrijgen omtrent de mechanische stabiliteit van de femorale prothesen en door middel van histologisch onderzoek gegevens te verkrijgen over de mate van ingroei van de bottransplantaten. De geiten werden 6 of 12 weken gevolgd. De gemeten subsidence ofwel axiale translatie was , in zowel de 6- als 12-weken groep, zeer consistent tussen 0.10 en 0.15 mm. Deze verplaatsingen klein waren ten opzichte van de direct post-operatief gemeten verplaatsingen (Hoofdstuk 4), doch de migratie welke onder hoge belastingen toch optrad gaf aan dat het incorporatie proces van het transplantaat niet volledig afgerond was na 12 weken. De gemeten rotaties vertoonden minder consistente waarden, maar de trend kwam

overeen met de bovenstaande bevindingen. Bij histologische analyse was er duidelijk sprake van revascularisatie van het transplantaat en botombouw. Er werd een gemengd beeld gezien van resten getransplanteerde bot in combinatie met nieuw gevormd bot. Dit werd veroorzaakt door botappositie op het getransplanteerde bot alsmede door resorptie van het getransplanteerde bot. Er was duidelijk meer botnieuwvorming in de 12 weken groep, maar het ingroei- en ombouwproces was nog niet voltooid. Geconcludeerd werd dat de stabiliteit van de gecementeerde femorale prothesen binnen een mantel van getransplanteerd bot voldoende was om deze transplantaten te laten ingroeien.

In Hoofdstuk 6 is hetzelfde in vivo diermodel gebruikt waarbij nu de ongecementeerde titanium prothese geplaatst werd, welke volledig was voorzien van een hydroxy-apatiet coating. Ook in deze studie werden de mechanische stabiliteit en de histologie onderzocht na 6 en 12 weken. Het aantal uitvallers was vrij groot. Zo konden maar 4 van de 8 ingezette prothesen voor de mechanisch studie worden getest; er was maar één test mogelijk na 6 weken implantatie-duur en er waren drie testen mogelijk na 12 weken implantatieduur. Wel bleken alle geteste prothesen zeer stabiel te zijn voor subsidence (axiale translatie, max. 0.036 mm) en axiale rotatie (max. 0.17 graden). Zelfs onder herhaalde belastingscycli bleef dit gehandhaafd. Ten opzichte van de resultaten onmiddelijk post-operatief was er sprake van een dramatische verbetering van de stabiliteit (Hoofdstuk 4). Histologisch onderzoek liet in alle gevallen revascularisatie en ombouw van het transplantaat zien. Opnieuw werd een mengeling gezien van resten van getransplanteerd bot in combinatie met botnieuwvorming. Ingroei van transplantaat werd vooral gezien in de proximale gebieden. Resorptie van transplantaat vond vooral plaats ter hoogte van het midschacht gebied van de prothese alsook ter hoogte van de meer distaal gelegen gedeelten. Aangetoond kon worden dat het geimpacteerde transplantaat een belaste ongecementeerde femorale prothesen een voldoende stabiliteit kon geven zodat ingroei van het transplantaat mogelijk was. Het aantal uitvallers was echter hoog, mogelijk als gevolg van de slechte initiële stabiliteit. De techniek moet zeker verder worden verbeterd.

Gebaseerd op het instrumentarium dat werd ontwikkeld voor de dierexperimenten werd een set voor humane klinische toepassing ontwikkeld (X-Change Revision Instruments), in samenwerking met het Princess Elizabeth Orthopaedic Hospital te Exeter (U.K.) en Howmedica International. In Hoofdstuk 7 worden onze eerste klinische resultaten beschreven bij de eerste 10 patiënten met een gemiddelde follow-up van 24 maanden. Het gebruik van een geimpacteerd gefragmenteerd bottransplantaat in gevallen met ernstig femoraal botverlies lijkt een veelbelovende optie te zijn. De juiste waarde van deze techniek voor de kliniek kan alleen worden aangetoond door studies met een langere follow-up.

Dankwoord

Bij de speurtocht naar een opleidingsplaats Orthopedie bleek voor een student Medicijnen zonder verdere kwalificaties de voordeur van de afdeling Orthopedie op slot te zitten. De deur van het Laboratorium voor Experimentele Orthopedie bleek echter ruim open te staan. Op deze wijze werd met het in Hoofdstuk 2 beschreven onderzoek de basis voor de gehele verdere promotie gelegd.

In eerste instantie werd deelgenomen aan het "cementproject" van drs. Ir. Pieter Spierings. Beste Pieter, ik waardeer nog steeds de wijze waarop je me met de materie vertrouwd hebt gemaakt en hebt geïntroduceerd in de wereld van het onderzoek. Gaandeweg dit project volgde de introductie bij de huidige promotoren Prof. Dr. T.J.J.H. Slooff en Prof. Dr. Ir R. Huiskes.

Na afgestudeerd te zijn als medicijnman was het mogelijk om mij gedurende bijna anderhalf jaar te verdiepen in de problematiek rond de revisie-chirurgie. Dit was financieel mogelijk door een subsidie van Economische Zaken voor dit project. Daarnaast heb ik een jaar als Agnio Orthopedie gefungeerd op een plaats van de universitaire assistenten onderzoekspool. Voor de toenmalige groep assistenten ben ik waarschijnlijk een erg vreemde eend in hun bijt geweest.

De beide promotoren Prof. Dr. T.J.J.H. Slooff en Prof. Dr. Ir. R. Huiskes wil ik hartelijk danken voor de grote betrokkenheid bij, kennis van, en enthousiasme voor mijn onderzoeksproject. De mate van vrijheid welke mij werd gegeven om het onderzoek uit te voeren, nadat de onderzoekslijnen eenmaal waren uitgezet, heb ik zeer gewaardeerd.

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Mijn opleider Heelkunde van het Medisch Spectrum te Enschede, Dr. I.J. Hoogendam, alsmede de overige stafleden, wil ik hartelijk danken voor hun altijd soepele houding aangaande onderzoeksactiviteiten. Mede hierdoor was het mogelijk een tweetal internationale voordrachten te houden tijdens de vooropleiding Heelkunde, en tevens het onderzoek op afstand te coachen. Het was ook prettig te ervaren dat de collega-assistenten hiervoor veel begrip toonden.

Zonder de hulp van drs. H. de Boer was scanning elektronen microscopie niet mogelijk geweest.

Met Sander Bierkens werd prettig samengewerkt bij de praktische experimenten met de niersteenvergruizer. Met Geert Smits werden verhelderende discussies gevoerd over de achtergronden van de niersteenvergruizer.

Dit project werd mede mogelijk gemaakt door deelsponsering door Ortech B.V., Stryker Europa B.V., Merck, Howmedica Nederland en Howmedica International, waarvoor dank.

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Curriculum vitae

Berend Willem Schreurs werd geboren op 2 juni 1957 te Winterswijk. Het Atheneum B diploma werd behaald in 1975, nadien wilde hij Medicijnen studeren doch werd hierin gedwarsboomd door de numeris fixus.
Na een jaar de HBO-opleiding tot Medisch Analist te hebben gevolgd (SLP te Hengelo (Ov.)), bezocht hij van 1976 tot 1980 de opleiding voor Fysiotherapie te Enschede (Stafto). Na het afstuderen was hij gedurende een jaar werkzaam als fysiotherapeut bij de Winterswijkse Ziekenhuizen.
Het bloed kroop echter waar het niet gaan kon, daarom begon hij in 1981 alsnog aan de studie Medicijnen te Nijmegen (KUN). Het kandidaats- (1983) en het doctoraalexamen (1985) werden cum laude behaald. Ter financiering van de studie was hij in deze periode part-time werkzaam als fysiotherapeut.
Vervolgens deed hij ter opvulling van de wachttijd voor de co-assistentschappen een wetenschappelijke stage bij het Laboratorium voor Experimentele Orthopedie (Prof.Dr. T. Slooff, Prof.Dr.Ir. R. Huiskes). Onder leiding van drs.Ir. P. Spierings werd onderzoek verricht naar de porositeit van botcement.
In 1988 werden zowel het arts-examen als het E.C.F.M.G. examen (het zogenaamde Amerikaanse arts-examen) met succes afgelegd.
Van augustus 1988 tot januari 1990 was hij opnieuw werkzaam op het Laboratorium voor Experimentele Orthopedie, waarbij hij als Agnio Orthopedie een volledige onderzoekplaats kreeg teneinde zich te verdiepen in de problemen rond de revisie-chirurgie. In deze periode werd de basis gelegd voor dit promotie-onderzoek.
In het kader van de opleiding tot Orthopedisch chirurg werd op 1 januari 1990 gestart met de vooropleiding Heelkunde (opleider Dr.I.J. Hoogendam, Medisch Spectrum Twente, Enschede). Vanaf 1992 is hij bezig met de vervolgopleiding Orthopedie (opleider Prof.Dr. R.P.H. Veth).

STELLINGEN

behorende bij het proefschrift

Reconstructive options in revision surgery
of failed total hip arthroplasties

B.W. Schreurs

Nijmegen, 9 december 1994

Het is mogelijk bij femorale reconstructies intramedullair botverlies te herstellen met geimpacteerde botchips, waarna incorporatie van dit transplantaat optreedt.
(dit proefschrift)

De aanmaak van botcement dient bij voorkeur onder vacuüm te gebeuren.
(dit proefschrift)

Bij een patiënt met een gefaalde totale heupprothese dient een grondige re-visie van de gehele problematiek vooraf te gaan aan de revisie operatie.

A periodic yearly follow-up of patients with a total hip arthroplasty is necessary to prevent extensive loss of bone.
(T.J.J.H. Slooff in Bone Implant Grafting, ed. J. Older, Springer Verlag 1993)

Perhaps, total hip replacement should be seen from the start as a multi-stage treatment.
(R. Huiskes in Acta Orthop. Scand., 64, 699-716, 1993)

Vooralsnog blijken de lange termijnsresultaten behaald met gecementeerde femorale componenten niet te worden benaderd door ongecementeerde componenten.

Wetenschappelijk onderzoek dient een clinicus bij voorkeur niet te verrichten in een witte jas.

De anatomische kennis wordt sterk verbeterd door het assisteren bij orthopedisch-oncologische dissecties.

Nu academische medische centra zowel to*p*-klinische zorg als to*p*referentiezorg moeten gaan leveren bij steeds grotere budgettaire problemen lijkt een veranderde spelling van beide begrippen in de toekomst onvermijdelijk.

Hippocrates still shows the way to success for doctors as we near the year 2000: cure occasionally, relieve frequently and comfort always. (R.H. Ruffner, LAD Lustrumsymposium 1993)

De promotie van het "Achterhookse" dialect door de popgroep Normaal is dermate effectief geweest dat zelfs wetenschappelijke congressen in dit dialect worden aangekondigd. (Congres Nederlandse Orthopaedische Vereniging 1992 te Enschede, titel "Kiek'n wat wodt")

Veel promovendi hopen dat hun promotie sneller kan worden afgerond met een snellere computer doch onderschatten de promovendus als beperkende factor.

Gezien de grote financiële belangen van de fabrikanten van wegwerpluiers zijn, naast de Huggies en Pull-Ups, binnenkort luiers met vleugels te verwachten, hetgeen de taak van huismoeders en vaders aanzienlijk zal verlichten.

Hoewel de momenteel in de auto-wereld magische term air-bag prima zou kunnen worden vertaald met windbuil lijkt de invoering hiervan uit marketing-technisch oogpunt onwaarschijnlijk.